COBE SPECTRA™

APHERESIS SYSTEM

OPERATOR'S MANUAL

For Use with Software Program Revisions 3.0 through 3.9

Reorder No. 700558-004
Part No. 777012-012
1991/02

CLI 121393

This *COBE Spectra™ Operator's Manual* was printed in the USA.

Questions or comments about this publication can be directed to:

COBE

COBE BCT, Inc.
Blood Component Technology
BCT Marketing Dept.
Lakewood, Col rado 80215-4407
USA
(303)232-6800

HOW TO USE THIS MANUAL

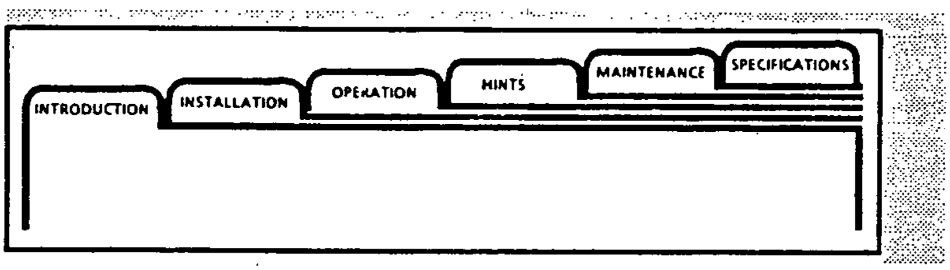
PURPOSE OF MANUAL

The purpose of the *COBE Spectra Operator's Manual* is to provide you, the Spectra operator, with the information you need to operate the COBE Spectra™ Apheresis System safely, reliably, and efficiently.

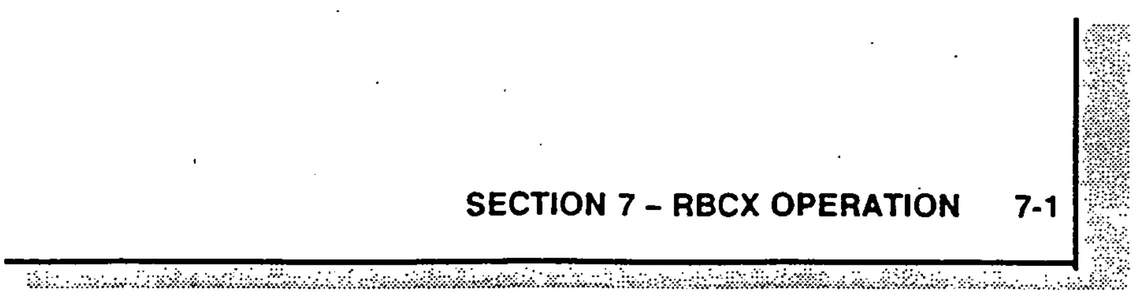
INDEXING

To locate the desired information in this *Manual*, use the detailed Table of Contents, the Tab Dividers, and/or the trailers on the bottom of each page.

Dividers with Tabs are provided to select the desired section or appendix.



Page trailers identify Section Name and Number (or Appendix Name and Letter), and Page Number.



SECTION CONTENTS

The COBE Spectra™ Apheresis System is a blood component separator that allows you to collect blood components from donors and perform therapeutic blood component exchange and blood product depletion/removal procedures for patients. For a detailed description of the Spectra Apheresis System, see SECTION 1 – INTRODUCTION.

The remainder of this section provides brief descriptions of each of the *Manual's* sections and appendixes to familiarize you with the contents of the *Manual* and help you determine which section to consult for specific types of information. If you have acquired this *Manual* along with the Spectra Enhancement Package, also review the following section, **DIFFERENCES BETWEEN 2.5 AND 3._ VERSIONS OF *MANUAL*.**

In addition to reviewing the remainder of this section, it is important that you read and thoroughly understand the information in the *Manual* before attempting to use the Spectra Apheresis System.

SECTION 1 – INTRODUCTION

This section provides

- An overall description of the physical components of the Spectra system, including
  - Its six blood tubing sets
  - The COBE Spectra™ Single-Needle Set
  - The centrifuge chamber
  - The front panel
  - The control panel
  - The COBE Spectra™ Return Flow Controller

  This information will help you learn the names and purposes of each of the Spectra system's physical components.

- A description of how the Spectra system functions, including general information on
  - How the system separates blood into its components
  - How the system's pumps and valves control anticoagulant, inlet flow, fluids being returned to the donor/patient, and blood components being collected or removed
  - How the system's safety sensors and control panel alarms/warnings help ensure its safe operation
  - Your ability to run the system in an Automatic or Manual mode. For additional information on how the control panel keys function in Manual and Automatic operation, see APPENDIX C – MANUAL AND AUTOMATIC OPERATION.
  - How the system manages anticoagulation of the extracorporeal blood circuit

- The system's nine configurable parameters. See the sections of APPENDIX A – KEYBOARD SELECTIONS that discuss Configuration Selection Messages for information on how to set these configurable parameters.

This information will help you understand how the Spectra system and its components function.

SECTION 2 – INSTALLATION

This section provides information on

- The environmental requirements, packing list, assembly instructions, moving instructions, and storage instructions for the Spectra Apheresis System
- The packing list and installation instructions for the Spectra Single-Needle Return Flow Controller
- Instructions for how to return used COBE products

SECTIONS 3A TO 8 – SPECTRA PROCEDURES

These sections provide you with step-by-step procedures on how to use the Spectra Apheresis System, a dual-stage or single-stage channel filler; a collect, TPE, or RBCX flow path overlay; and the appropriate disposable blood tubing set to perform one of the following apheresis procedures:

- Dual-needle or single-needle Extended Life Platelet (ELP™) collection procedures to collect donor platelets for storage up to 5 days. When desired, plasma can be collected concurrently with the platelets.
- Dual-needle or single-needle Platelet collection procedures to collect donor platelets for storage up to 24 hours. When desired, plasma can be collected concurrently with the platelets.
- Platelet depletion patient procedures
- Dual-needle or single-needle therapeutic plasma exchange (TPE) patient procedures
- Red blood cell exchange (RBCX) patient procedures
- White blood cell (mononuclear cell or granulocyte) removals

To help you understand how the Spectra system responds to each action you take during any of these procedures, the left-hand column of each section shows each operator action and the right-hand column shows the corresponding system action.

SECTION 9 – DIAGNOSTICS

The Spectra Apheresis System provides you with an opportunity to verify that the key Spectra alarm systems are fully operational before beginning each donor/patient procedure. This section provides you with step-by-step procedures on how to carry out these alarm tests.

SECTION 10 - HELPFUL HINTS

This section provides you with a number of step-by-step procedures that may be useful during some or all of the apheresis procedures detailed in Sections 3A through 8 as well as definitions of the abbreviations used in this *Manual*. See the Table of Contents entries for SECTION 10 or the first page of SECTION 10 for a complete list of these procedures.

SECTION 11 - TROUBLESHOOTING

The Spectra Apheresis System has a built-in safety system that signals alarm, warning, and operator-attention conditions via a) an operator message that is displayed on the control panel, b) an audible alarm, and c) an LED light. The severity of the condition determines the type of audible alarm and whether a red alarm LED or yellow warning LED is lighted.

For each operator alarm, warning, or attention message, this section contains an alphabetical-order entry that provides information on

- The operator message as it appears on the control panel display
- Whether the LED light is red or yellow
- The type of audible alarm produced
- The actions that the Spectra system automatically takes in response to each alarm or warning condition
- Probable causes of the alarm, warning, or operator-attention condition
- Actions you should take in response to each probable cause

For a complete list of the alarm, warning, and operator-attention messages covered in SECTION 11, see either Table 11-1, Spectra Alarms, at the beginning of SECTION 11 or the entries for SECTION 11 in the Table of Contents. Note that the right-hand column of Table 11-1 tells you what page of SECTION 11 to refer to for detailed information on each alarm, warning, or operator-attention message as well as, when appropriate, what pages in SECTION 12 - RECOVERY PROCEDURES and SECTION 13 - MAINTENANCE to refer to for additional information.

SECTION 12 - RECOVERY PROCEDURES

This section contains step-by-step recovery procedures that are intended to help you bring the Spectra Apheresis System back to safe operating conditions after, for example, an alarm has been cleared. This section also includes steps for

- Converting a dual-needle Platelet or TPE procedure to a single-needle procedure after the procedure has already been started as a dual-needle procedure
- Backing out of a Platelet or TPE procedure that was begun as a single-needle procedure that you want to continue as a dual-needle procedure.

COBE recommends that you read and understand all of the recovery procedures.

See the Table of Contents entries for SECTION 12 or the first page of SECTION 12 for a complete list of the recovery procedures covered in this section.

SECTION 13 - MAINTENANCE

This section provides information on the

- Operator maintenance procedures for the Spectra Apheresis System
- Operator maintenance procedures for the Spectra Single-Needle Return Flow Controller
- Technician maintenance procedures for the Spectra Apheresis System

SECTION 14 - SPECIFICATIONS

This section provides the following characteristics, performance, and conditions specifications for the Spectra Apheresis System:

- Physical
- Environmental
- ac Power
- Electrical Safety
- Safety Certifications
- Flow Rates and Speeds
- Return Flow Controller
- Blood Tubing Sets
- Centrifuge
- Safety
- Sensors
- AC Pump Alarm Responses

APPENDIX A - KEYBOARD SELECTIONS

APPENDIX A provides detailed information on the Spectra system's keyboard selections available via the VALVE, CHANGE MODE, and MENU ON/OFF keys. This section will help you learn how to use these keys.

The VALVE key allows you to both select which valve you want to move and control each valve's position. Table A-1 provides information on the valve position changes that are valid during specific Spectra operating modes or states.

The CHANGE MODE key allows you to change between the Load Set, Prime, Run, Rinseback, Unload Set, and Diagnostic modes. Table A-2 provides information on what mode changes are valid during specific Spectra operating modes or states.

The MENU ON/OFF key allows you to

- Enter donor/patient data

- Access the pressure sensor display so that you can monitor the donor/patient access and return pressures
- Access the Collect Concentration Monitor display so that you can
  - Turn off the CCM warnings for the current procedure
  - View the current platelet yield collected at any point in a procedure
  - View the CCM predicted yield for the end of the procedure
- Remove air from the inlet and return air chambers
- Turn the centrifuge strobe off and on
- Set configurable parameters. See the **SETTING CONFIGURATION VALUES** section of SECTION 1 – INTRODUCTION for more information on setting these configurable parameters.
- When the Single-Needle Option is installed
  - View the *single-needle statistics message*
  - Convert a Platelet or TPE procedure begun as a dual-needle procedure to a single-needle procedure
  - Cancel a previously requested dual-needle to single-needle conversion

APPENDIX B – DATA INPUT LIMITS

APPENDIX B explains the limits that the Spectra Apheresis System places on operator-selectable parameters like target run time and some of the calculated variables like the AC flow rate to ensure that the system is operated in a safe manner. Table B-1 covers the initial or default settings that the Spectra system provides for parameters you can enter during donor/patient data entry. It also covers the maximum and minimum absolute limits that the system places on the values you can assign these parameters.

APPENDIX C – MANUAL AND AUTOMATIC OPERATION

APPENDIX C explains how the FLOW, RATIO, and SPIN keys on the control panel function in Manual and Automatic operation and how single-needle flow is controlled during Manual and Automatic operation.

DIFFERENCES BETWEEN 2.5 AND 3.__ VERSIONS OF THIS MANUAL

If you had the COBE Spectra™ Apheresis System before acquiring the Spectra Enhancement Package, you need to review this section of the *Manual* to understand how this version of the *Manual* was revised to reflect changes made for the Spectra Enhancement Package (which includes 3.__ Spectra software) as well as to incorporate other changes designed to improve the *Manual*'s value to its users.

SPECTRA ENHANCEMENT PACKAGE

The Spectra Enhancement Package provides the following enhancements to the operation of the Spectra system:

- **Single-needle operation for Extended Life Platelet (ELP™) collection for 5-day platelet storage and Platelet collection for 24-hour storage.** Being able to do single-needle ELP and Platelet collections makes your donor management easier because it allows donors with only one access to become part of your donor pool. The extracorporeal blood volume for each single-needle draw and return cycle is only 81 ml of blood, keeping the total extracorporeal blood volume for these procedures between 145 and 226 ml.

  To allow single-needle ELP and Platelet collections to be carried out, the Spectra Enhancement Package includes

  - 3.__ *software changes*
  - For single-needle ELP procedures, a *single-needle disposable ELP blood tubing set*. This set incorporates a single donor-access needle and a single-needle bag. The bag holds the blood components removed from the donor during the draw phase of a single-needle procedure for return to the donor during the return phase.
  - For single-needle Platelet procedures, the *COBE Spectra™ Single-Needle Set*. This set incorporates a single-needle bag and a "Y" connector, which are used to convert a dual-needle Platelet blood tubing set to a single-needle Platelet tubing set.
  - The *COBE Spectra™ Single-Needle Return Flow Controller*. The Return Flow Controller holds the single-needle bag and provides controlled pressure on the bag to produce the desired return flow during the return phases of a single-needle procedure.

- **Concurrent plasma collection.** The 3.__ Spectra software allows plasma to be collected concurrently during dual-needle and single-needle ELP and Platelet collection procedures. This plasma can be used, without any secondary processing, for source plasma, liquid plasma, and fresh frozen plasma. Prescribed amounts of plasma can be collected, with the amount of plasma collected based on either the size of the donor or a percentage of the donor's total blood volume. During concurrent plasma collection, the Spectra system will calculate the actual amount of plasma in the plasma collection bag.

- **Improved AC infusion rate management.** The 3.__ Spectra software has changed the way the AC infusion rate is managed. Prior to 3.__ software, the Spectra system managed the AC infusion rate by controlling the amount of anticoagulant pumped by the AC pump. With 3.__ software, the system manages the AC infusion rate by controlling the amount of anticoagulant actually returned to the donor or patient.

- **Increased platelet yield procedures.** By following the modified AC ratio, AC infusion rate, concurrent plasma collection, or high inlet flow rate procedures, you will increase the number of donors who can provide double-platelet products or, alternatively, you can significantly decrease the amount of time required for ELP and Platelet collection procedures.

  These increased platelet yield procedures, which are all 3.__ software changes, include

  - Several *anticoagulant ratio options*. The Medium option provides for a 25% higher platelet yield, and the High option provides for a 45% higher platelet yield.
  - *Configuration of true AC infusion rate*. During manufacturing, the AC infusion rate for ELP and Platelet collection procedures is set to 0.8 ml/min/liter of total blood volume. When medically appropriate, the medical director can change the AC infusion rate to a value between 0.8 and a maximum of 1.10 ml/min/liter of total blood volume. Increasing the AC infusion rate increases the amount of blood processed, which, in turn, increases the platelet yield. For additional information on how the configuration of the AC infusion rate affects the amount of blood processed, see the **ANTICOAGULATION** section of SECTION 1 – INTRODUCTION.
  - *Concurrent plasma collection*, allows more blood to be processed, which, in turn, increases the platelet yield by 5% to 20%. Concurrent plasma collection allows more blood to be processed because some of the anticoagulant added to the donor's inlet flow is removed to the plasma collect bag. This means that the donor's inlet flow rate can be increased without an equivalent increase in the rate of anticoagulant flow back to the donor. When you select to collect plasma concurrently with platelets, the Spectra system automatically increases the inlet flow rate based on donor parameters.
  - A *high inlet flow rate protocol*, which allows for an inlet flow rate as high as 80 ml/min, which, in turn, increases the platelet yield.

- **AC status message**. This displays the *current* AC infusion rate as well as the *predicted* number of milliliters of anticoagulant in the collect and plasma bags at the end of the run.

- **Single-needle operation for therapeutic plasma exchange (TPE) procedures.** Being able to do single-needle TPE procedures makes it easier to manage patients who require therapeutic plasma exchange but who do not have two viable access sites and for whom chronic vascular access procedures are not appropriate. The extracorporeal blood volume for each single-needle draw and return cycle is only 84 ml of blood, keeping the total extracorporeal blood volume for these procedures between 184 and 254 ml.

  To allow single-needle TPE procedures to be carried out, the Spectra Enhancement Package includes

  - *3.__ software changes*
  - The *Single-Needle Set*. This set incorporates a single-needle bag and a "Y" connector, which are used to convert a dual-needle TPE blood tubing set to a single-needleTPE tubing set.
  - The *Single-Needle Return Flow Controller*. The Return Flow Controller holds the single-needle bag and provides controlled pressure on the bag to produce the desired return flow during the return phases of a single-needle procedure.

- **Red blood cell exchange (RBCX) procedure.** With Spectra RBCX procedures, if the volume of the replacement fluid is known, you need only enter that volume, the patient's current hematocrit, the average hematocrit of the replacement fluid, and the attending physician's prescription for the desired end hematocrit and desired fluid balance. The Spectra system will then perform the necessary calculations to determine the appropriate pump speeds and other operating parameters necessary to achieve the desired results.

On the other hand, the attending physician may want to calculate the amount of red blood cell replacement fluid to order a day or two before an RBCX procedure is performed. In such situations, you can determine the amount of replacement fluid required without connecting the patient to the Spectra system and without actually running an RBCX procedure. You do this by using the Spectra system's control panel to enter the patient's hematocrit, the average hematocrit of the replacement fluid, the attending physician's prescription for the desired end hematocrit, the desired fluid balance, and the desired percentage of defective red blood cells remaining at the end of the procedure. The system will then use this information to calculate the volume of replacement red blood cells needed.

To allow RBCX procedures to be carried out, the Spectra Enhancement Package includes

- *3.__ software changes*
- *A disposable RBCX blood tubing set*
- *RBCX flow path overlay.*

- **Granulocyte removal procedure.** The Spectra system's white blood cell (WBC) removal procedure now allows you to choose between a mononuclear cell (MNC) and granulocyte [polymorphonuclear cell (PMN)] removal. Depending upon the type of WBC procedure chosen and subject data entered, the Spectra system calculates the optimum pump flow rates and centrifuge speed for that procedure.

  To allow granulocyte collections to be carried out, the Spectra Enhancement Package includes 3.__ software changes.

- **Configurable parameter changes.** With 3.__ Spectra software, changes to the system's nine configurable parameters always affect the current procedure immediately.

- **Access/return pressure settings.** Spectra 3.__ software allows you to
  - Monitor the donor/patient access and return pressures
  - Set low and high limits for the access and return pressures.

CHANGES MADE TO 3.__ VERSION OF *SPECTRA OPERATOR'S MANUAL*

To accommodate the changes made in the operation of the Spectra Apheresis System by the Spectra Enhancement Package and to incorporate other changes designed to improve the *Manual*'s value to its users, this version of the *Manual* was revised as follows:

- The ELP collection, Platelet collection, and TPE sections (Sections 3, 4, and 6) of the 2.5 version of the *Manual* were each divided into two subsections: one for dual-needle operation (Sections 3A, 4A, and 6A) and one for single-needle operation (Sections 3B, 4B, and 6B).

- The following sections, which are not in the 2.5 version of the *Manual*, were added:
  - Section 7 – RBCX Operation
  - Section 10 – Helpful Hints

  See **HOW TO USE THIS MANUAL** for descriptions of the contents of these sections.

- Every other section in the *Manual* was changed to some degree between versions 2.5 and 3.__, with the most extensive changes being in

  - Section 1 – Introduction
  - Section 2 – Installation
  - Section 8 – WBC Operation
  - Section 11 – Troubleshooting
  - Section 12 – Recovery Procedures
  - Section 13 – Maintenance
  - Appendix A – Keyboard Selections

  See **HOW TO USE THIS MANUAL** for descriptions of the contents of these sections.

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INDICATIONS

The COBE Spectra™ Apheresis System is prescribed for use in apheresis procedures involving donors and patients.

CONTRAINDICATIONS

There are no known contraindications for use of the COBE Spectra Apheresis System, except those associated with the infusion of solutions and replacement fluids as required by the procedure and those associated with all types of automated apheresis systems.

WARNINGS

1. DANGER - EXPLOSIVE ATMOSPHERE; DO NOT USE THE COBE SPECTRA APHERESIS SYSTEM IN AN EXPLOSIVE ATMOSPHERE.
2. DO NOT USE COBE SPECTRA APHERESIS SYSTEM UNDER THE COMBINATION OF THE FOLLOWING EXTREME OPERATING CONDITIONS:
   - ROOM TEMPERATURE IS GREATER THAN 27.5°C (81°F).
   - CENTRIFUGE SPEED IS 2400 RPM.
   - PUMPS ARE PAUSED.

   AT THESE CONDITIONS, TRANSIENT WARMING TO TEMPERATURES ABOVE 42°C (107°F) CAN OCCUR IN SPECIFIC AREAS OF THE CENTRIFUGE LOOP. EXPOSURE TO THESE TEMPERATURES MAY DAMAGE BLOOD COMPONENTS CONTAINED IN THESE AREAS. APPROXIMATELY 2 ml OF BLOOD COMPONENTS CAN BE AFFECTED.

   THE DECISION TO RUN AT OR BEYOND THESE CONDITIONS IS THE RESPONSIBILITY OF THE PHYSICIAN.
3. DO NOT USE OPERATING OR MAINTENANCE PROCEDURES OTHER THAN THOSE PUBLISHED BY COBE LABORATORIES, INC., OR USE ACCESSORY DEVICES NOT RECOMMENDED BY COBE. TO DO SO MAY RESULT IN DONOR/PATIENT INJURY OR LOSS OF LIFE.

   COBE will not be responsible for donor/patient safety if the procedures to operate, maintain, and calibrate the COBE Spectra Apheresis System are other than those specified by COBE Laboratories, Inc. Persons performing the procedures must be appropriately trained and qualified.

   Any equipment modifications must be performed by qualified persons and be approved in writing by COBE Laboratories, Inc.
   All electrical installations must comply with all applicable local electrical codes and COBE specifications.
4. DO NOT USE ALTERNATE POWER PLUGS OR ADAPTERS THAT DISCONNECT THE GREEN WIRE SAFETY GROUND.
5. TO AVOID INADVERTENT REMOVAL OF ADDITIONAL BLOOD FROM DONOR/PATIENT OR RETURN OF FLUIDS TO DONOR/PATIENT, ENSURE ACCESS IS DISCONNECTED BEFORE STARTING RINSEBACK.
6. ALARM SYSTEM IS INACTIVATED WITH POWER OFF. WATCH FOR AIR IN THE RETURN LINE WHILE RETURNING BLOOD TO DONOR/PATIENT. IF YOU SEE AIR IN LINE, DISCONTINUE MANUAL RINSEBACK IMMEDIATELY.

7. ONCE FLUID HAS ENTERED THE TUBING SET, DO NOT DISTURB SENSORS IN PRESSURE SENSOR HOUSINGS BECAUSE THIS WILL PREVENT TRANSDUCERS FROM MONITORING PRESSURES ACCURATELY.

8. BEFORE EACH USE OF THE COBE SPECTRA APHERESIS SYSTEM, INSPECT ALL LINES, ESPECIALLY THOSE IN THE CENTRIFUGE AND ON THE FRONT PANEL, TO ENSURE THEY ARE NOT KINKED. LINES THAT ARE OCCLUDED, OR PARTIALLY OCCLUDED, MAY LEAD TO THE PROCEDURE NOT OPERATING CORRECTLY OR TO POSSIBLE FLUID IMBALANCE.

9. DO NOT CONNECT DONOR/PATIENT BEFORE RUNNING ALARM TESTS.

10. IF ANY OF THE FOLLOWING OCCUR, THE DISPOSABLE DUAL-NEEDLE AND SINGLE-NEEDLE EXTENDED LIFE PLATELET (ELP) BLOOD TUBING SETS ARE NO LONGER FUNCTIONALLY CLOSED AND PRODUCT SHOULD NOT BE STORED BEYOND 24 HOURS:
    - FAILURE IN FIRST ATTEMPT TO SUCCESSFULLY INSERT ACCESS NEEDLE
    - DISCONNECTION OF ACCESS NEEDLE FROM TUBING SET
    - USE OF INJECTION SITE ON ACCESS MANIFOLD FOR BLOOD SAMPLES OR INFUSION OF MEDICATION OR PARENTERAL SOLUTIONS
    - DISCONNECTION OF EITHER PLASMA OR PLATELET COLLECT BAG BEFORE IT IS SEALED
    - USE OF SAMPLE SITE ON PLATELET COLLECT BAG FOR BLOOD SAMPLES OR INFUSION OF MEDICATION OR PARENTERAL SOLUTIONS
    - COMPROMISE IN INTEGRITY OF TUBING SET FOR ANY REASON
    - USE OF LUER CONNECTION BELOW PLATELET COLLECT BAGS FOR COLLECTION OF BLOOD SAMPLES OR INFUSION OF MEDICATION OR PARENTERAL SOLUTIONS.

11. BLOOD COMPONENTS SHOULD BE INSPECTED FOR BACTERIAL GROWTH BEFORE TRANSFUSION IN ACCORDANCE TO APPLICABLE STANDARDS (FOR EXAMPLE, THE AMERICAN ASSOCIATION OF BLOOD BANK'S *STANDARDS FOR BLOOD BANKS AND TRANSFUSION SERVICES*).

12. THE EXTENDED STORAGE OF PLATELETS AT 22°C REQUIRES STRICT AWARENESS OF ANY POSSIBLE SOURCES OF EXTRINSIC CONTAMINATION. RIGOROUS ATTENTION SHOULD BE PAID TO PROPER VENIPUNCTURE SITE SELECTION AND DECONTAMINATION.

13. THE ADDITION OF CALCIUM GLUCONATE OR OTHER CALCIUM SALTS TO FRESH FROZEN PLASMA MAY CAUSE CLOTTING IN THE REPLACEMENT FLUID.

    BLOOD COMPONENTS CONTAINING FORMED ELEMENTS ARE NOT RECOMMENDED AS REPLACEMENT FLUIDS EXCEPT FOR RED BLOOD CELL EXCHANGE (RBCX) PROCEDURES.

14. FLUID IMBALANCES CAN BE CAUSED BY THE FOLLOWING:
    - USING INADEQUATELY PRIMED OR CLOTTED MICROAGGREGATE FILTERS ON REPLACEMENT LINE
    - ADMINISTERING REPLACEMENT FLUIDS THAT ARE NOT AT ROOM TEMPERATURE
    - USING IMPROPERLY VENTED REPLACEMENT FLUID CONTAINERS
    - EQUIPMENT MALFUNCTION
    - IMPROPER LINE CLAMPING
    - DURING RED BLOOD CELL EXCHANGE PROCEDURES, USING AN INADEQUATELY PRIMED OR CLOTTED LEUKOCYTE-POOR RED BLOOD CELL FILTER ON THE REPLACEMENT LINE. REFER TO FILTER MANUFACTURER'S GUIDELINES TO BE SURE THAT THE FILTER CAN MEET REPLACEMENT FLUID FLOW RATES.

    MONITOR ALL SOLUTIONS AND PROCEDURES FOR CORRECT FLUID BALANCE.

15. MONITOR THE PATIENT CLOSELY FOR REACTIONS ANY TIME BIOLOGICALLY DERIVED REPLACEMENT FLUIDS ARE BEING USED.

16. BEFORE CONNECTING DONOR/PATIENT, CHECK ACCESS AND RETURN LINES FOR AIR. IF AIR IS PRESENT IN THESE LINES, DO NOT CONNECT DONOR/PATIENT. REMOVE AIR BEFORE STARTING PROCEDURE.
17. DO NOT UNLOAD DISPOSABLES IF DONOR/PATIENT IS CONNECTED TO THE COBE SPECTRA APHERESIS SYSTEM. IF DISPOSABLES ARE UNLOADED WHILE DONOR/PATIENT IS CONNECTED, ANTICOAGULANT AND OTHER FLUIDS MAY BE INFUSED THROUGH THE ACCESS AND RETURN NEEDLES.
18. IN MOST CASES, THERAPEUTIC PLASMA EXCHANGES WILL NOT SIGNIFICANTLY ALTER THE THERAPEUTIC EFFECT OF A PATIENT'S MEDICATIONS; HOWEVER, IT IS ADVISABLE TO OBTAIN A DETAILED DRUG HISTORY BEFORE EACH PROCEDURE. FOR THOSE DRUGS POTENTIALLY AFFECTED BY THERAPEUTIC PLASMA EXCHANGES, THE PHYSICIAN SHOULD EITHER ADJUST THE DOSES OR GIVE THE MEDICATIONS IMMEDIATELY AFTER THE PROCEDURE.
19. REPEATED DAILY THERAPEUTIC PLASMA EXCHANGES USING PLASMA-POOR REPLACEMENT FLUIDS WILL INCREASE THE DEPLETION OF THE PATIENT'S COAGULATION FACTORS.
20. STANDARD TRANSFUSION PRACTICES FOR CELLULAR COMPONENTS SHOULD BE USED DURING RED BLOOD CELL EXCHANGE (RBCX) PROCEDURES.
21. THE COBE SPECTRA APHERESIS SYSTEM DOES NOT DETECT DISCONNECTION OF RETURN NEEDLE FROM PATIENT/DONOR.
22. GEAR SHROUD SHOULD ONLY BE REPLACED BY A QUALIFIED SERVICE REPRESENTATIVE.
23. THE COBE SPECTRA APHERESIS SYSTEM MAY INTERFERE WITH EKG MONITORING WHEN A PATIENT IS SUMULTANEOUSLY UNDERGOING APHERESIS AND EKG MONITORNIG.
24. *FOR FEDERAL REPUBLIC OF GERMANY:*
    - THE CORRECT INPUT OF THE DATA RELEVANT TO SAFETY (AC PUMP, INLET PUMP, INLET:AC RATIO) MUST BE CHECKED OUT BY THE OPERATOR.
    - BESIDES THE DISPOSABLE ITEMS MENTIONED IN THE INSTRUCTIONS FOR USE, THE ONLY OTHER DISPOSABLE ITEMS THAT MAY BE EMPLOYED ARE THOSE HAVING A CERTIFICATION FROM A TESTING AGENCY LICENSED BY THE BUNDESMINISTER FÜR ARBEIT UND SOCIALORDNUNG (BMA) AND CORRESPONDING TO THE NOTIFICATION BY THE BMA OF 10 DECEMBER 1986. (CERTIFICATION OF TESTING FOR UNOBJECTIONABLE USABILITY WITH RESPECT TO SAFETY.)
    - THE MANUFACTURER, ASSEMBLER, INSTALLER OR IMPORTER REGARDS ITSELF AS RESPONSIBLE FOR EFFECTS ON THE SAFETY, RELIABILITY, AND PERFORMANCE OF THE DEVICE ONLY IF:
        - ASSEMBLY, EXPANSIONS, READJUSTMENTS, ALTERATIONS, OR REPAIRS ARE CARRIED OUT BY PERSONS AUTHORIZED BY THIS ENTITY, AND
        - THE ELECTRICAL WIRING OF THE ROOM CONCERNED CONFORMS TO THE REQUIREMENTS OF IEC SPECIFICATIONS, AND
        - THE DEVICE IS EMPLOYED IN ACCORDANCE WITH THE INSTRUCTIONS FOR USE.

PRECAUTIONS

1. Report immediately to the responsible service personnel any of the following conditions. DO NOT use the COBE Spectra Apheresis System until corrective action has been taken.

   - Damaged or worn power cord, plug, or receptacle
   - Switches that are loose or do not operate with a positive action
   - A system that has been subject to physical shock or liquid spills on the electronics housed under the covers of the system
   - A system that has given anyone an electrical shock while in use
   - A system that appears to be overheating

2. DO NOT run the centrifuge without a filler and channel installed.

3. Keep hair away from pump rollers to avoid the possibility of hair being caught.

4. The COBE Spectra Apheresis System has many safety features. However, a donor/patient reaction can occur rapidly. Therefore, it is imperative that the COBE Spectra Apheresis System and the donor/patient be monitored continuously.

5. Each operator should be thoroughly familiar with this *Operator's Manual*. All procedures should be performed by qualified medical personnel under the supervision of a physician. A qualified physician should be available to attend the donor/patient when an apheresis procedure is being performed.

6. Disposable products may be subject to occasional failure which could result in the loss of blood, loss of blood product, or introduction of air into the tubing set. It is very important that the operator carefully observe for leaks during priming and use of the set.

7. Due to the possible exposure to hepatitis virus, human immunodeficiency virus, and other infectious agents in the handling of extracorporeal blood circuits, adequate precautions should be taken at all times to prevent exposure to and transmission of such agents.

8. The type of anticoagulant described in this *Operator's Manual* is intended as a guideline only. ACD-A is the approved anticoagulant for ELP and Platelet collection procedures and the preferred anticoagulant for red blood cell exchange, therapeutic plasma exchange, and WBC removal procedures using the COBE Spectra Apheresis System. A suggested procedure when heparin must be used in anticoagulation for therapeutic plasma exchange is provided in SECTION 10 – HELPFUL HINTS of this *Manual*. For granulocyte (PMN) removal, hydroxyethyl starch/sodium citrate concentrate may be used where permitted. The exact type, amount, and rate of anticoagulant to be administered is the sole responsibility of the attending physician. All personnel involved with apheresis procedures should familiarize themselves with the anticoagulant manufacturer's product insert.

9. Use aseptic technique throughout all procedures.

10. Be careful not to stretch the tubes when folding dual-stage channel for installation in the centrifuge.

11. The blood and fluid pathways of the tubing sets are sterile and nonpyrogenic. Do not use a tubing set if the end caps are not in place.

12. The tubing sets are intended for single use only.

13. Patients or donors with impaired or abnormal citrate and/or calcium metabolism (e.g., liver and renal diseases) may present an increased risk of citrate sensitivity. For this reason, the attending physician

should assess the appropriateness of such patient or donors for apheresis and prescribe how they should be monitored during the apheresis procedure.

14. Ensure lines are attached to correct fluids when priming the COBE Spectra Apheresis System:

    - AC line to anticoagulant container
    - Inlet and return saline lines to normal saline container

15. Visually verify that fluid is flowing into the access, return, and AC drip chambers.

16. No pump rates are controlled automatically when the COBE Spectra Apheresis System is in Manual operation.

17. In Manual operation, flow rates can be entered that are outside of the performance specifications published in this *Manual*. COBE makes no accuracy claim for values outside of the specified performance range for each pump.

18. The Single-Needle Return Flow Controller is required to run a single-needle procedure. Do not attempt to install (activate) and run a single-needle procedure without a Single-Needle Return Flow Controller and appropriate disposables.

19. Be sure that the Single-Needle Return Flow Controller is mounted high enough to clear the control panel on the COBE Spectra Apheresis System. This will prevent inadvertent damage to either assembly when the control panel is swiveled.

20. When the Single-Needle Return Flow Controller is mounted on the right vertical segment of the IV pole on the COBE Spectra Apheresis System, carefully check door clearances when moving the system, as the Return Flow Controller must be rotated inward to clear some doorways.

21. For single-pass prime procedures, due to the limited volume capacity of the disposable set waste bags, the Platelet tubing set as adapted for single-needle procedures may only be primed a maximum of two times, and the Dual-Needle ELP, Platelet, TPE, RBCX, and WBC tubing sets may only be primed a maximum of three times.

22. Be sure all luer connections are secure.

23. It is the responsibility of the health care institution to adequately prepare and identify the product for return shipment.

ADVERSE EFFECTS

Be aware of possible donor/patient reactions. Some donor/patient reactions that have been previously reported for whole blood donations or apheresis procedures are anxiety, headache, lightheadedness, digit and/or facial paresthesia, fever, chills, hematoma, hyperventilation, nausea and vomiting, syncope (fainting), urticaria, hypotension, and allergic reactions. For red blood cell exchange procedures, also monitor the patient for symptoms of transfusion reaction. Be prepared to take appropriate action should any of these symptoms appear.

Reactions to transfused blood products may include fever, circulatory overload, shock, and allergic reactions, as well as transmission of infectious diseases, bacterial contamination, alloimmunization, and graft versus host disease. Platelet products are the most likely products to be contaminated with bacteria. (Source: *Circular of Information for the Use of Human Blood Components*, p. 25. American Red Cross, Council of Community Blood Centers, and American Association of Blood Banks, March 1989.)

If a sedimenting agent is used in granulocyte [polymorphonuclear (PMN)] removal procedures, all personnel involved in the PMN removal procedure should familiarize themselves with any adverse affects, warnings, and/or cautions in the product insert produced by the manufacturer of the sedimenting agent.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

SYMBOLS AND CERTIFICATION

If applicable, the following symbols may appear on or near the serial number label of this device.

 Type B  Type BF

1. These symbols indicate that the device is classified as either Type B or Type BF per BS5724 (IEC 601.1) standard for electrical safety. This classification is based on the degree of protection afforded against electrical shock, as defined in that standard.

2. This symbol indicates that consultation of the accompanying documents prior to equipment operation is critical to the safe operation of the device.

3. This symbol indicates that the device is drip proof under the applicable test requirements.

~

4. This symbol indicates that the device requires an alternating supply current.

5. This symbol indicates that conductors carrying high voltage are nearby and that these could be hazardous if contacted.

COBE Laboratories, Inc., and/or subsidiaries listed on the following page, accepts responsibility for the safety, reliability, and performance of this equipment only if operational procedures, calibrations, and repairs are carried out by appropriately qualified persons; if all equipment modifications are authorized in writing by COBE Laboratories, Inc.; and carried out by appropriately qualified persons; if the electrical installation of the relevant room complies with all applicable local electrical codes and IEC requirements; and if the equipment is used in accordance with the published instructions for use.

COBE Laboratories, Inc., and/or subsidiaries listed below will provide on request, for nominal cost, a service manual which contains all necessary circuit diagrams, component parts lists, calibration instructions and service information to enable appropriately qualified technical personnel to repair those parts of this equipment which COBE considers to be repairable.

SERVICE INFORMATION

Should you require technical assistance, contact your COBE Customer Engineering Representative as listed below.

For **Service** or to order **Parts** in the United States, contact:

COBE Laboratories, Inc.
(Order Department)
1185 Oak Street
Lakewood, Colorado 80215 USA
Phone: 800-525-COBE (2623)
Phone: 303-232-6800

For **Parts** and **Service** outside the United States, contact:

COBE Laboratories, Inc.
International Division
1185 Oak Street
Lakewood, CO 80215 USA
Phone: 303-232-6800
Cable: COBELAB
Telex: 4322040 COBE UI
FAX: 303-233-9069

S.A. COBE Laboratories, Europe N.V.
Kernreactorstraat 36
3903 LG Veenendaal
The Netherlands
Phone: 31-8385-15380
FAX: 31-8385-27941

COBE Laboratories, Inc
European Corporate Headquarters
172 Sterrebeekstraat
1930 Zaventem-Nossegem
Belgium
Phone: 32-2-725-3060 (Belgium/Luxembourg)
32-2-725-3333 (other European, African, & Middle Eastern countries)
Telex: 846-62947 COBE B
FAX: 32-2-721-0770

Parts and **Service** outside the United States, (continued):

COBE S.A.
37, Place de la Loire
Silic 180
94563 Rungis Cedex
France
Phone: 33-1-4687-6653
Telex: 842-263116 COBE F
FAX: 33-1-4687-9724

COBE Canada, Ltd.
80 Milner Avenue
Scarborough, Ontario M1S 3P8
Canada
Phone: 416-291-9655
FAX: 416-291-7670

COBE Laboratories, GmbH
Ammerthalstrasse 19
8011 Heimstetten, Munich
Federal Republic of Germany
Phone: 49-89-9000-000
Telex: 841-898892 COBE D
FAX: 49-89-9000-0050

COBE Laboratories, Pty. Ltd.
Unit 1
45 Chard Road, Brookvale
NSW, Australia 2100
Phone: 61-2-938-6611
FAX: 61-2-938-6434

COBE Laboratories, Ltd.
Athena 2, Olympus Business Park
Quedgeley, Gloucester, England GL2 6NF
Phone: 44-452-722070
Telex: 851-437194 COBE G
FAX: 44-452-720172

COBE Laboratories, K.K.
Yasuke Building 8F
1-19-6 Sekiguchi
Bunkyo-ku, Tokyo 112, Japan
Phone: 81-3-235-8871
FAX: 81-3-235-8874

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SECTION 1 - INTRODUCTION

INTRODUCTION

The *COBE Spectra Operator's Manual* is intended for the person who will be operating the COBE Spectra™ Apheresis System. The recommended procedures in this book have been developed and tested to provide safe, reliable, and efficient operation of the Spectra system. It is important that you, the operator, read and thoroughly understand the information in this *Manual* before attempting to use the Spectra system.

SYSTEM DESCRIPTION

The Spectra Apheresis System is intended to separate and collect blood components from both donors and patients. From donors, blood products are collected for transfusion to patients. The Spectra system can be used to collect leukocyte-poor, extended life platelets for transfusion to appropriate thrombocytopenic patients. If desired, plasma can be collected concurrently with platelets. The plasma thus collected is available for use as plasma or fresh frozen plasma. Alternatively, it may be used as source plasma for further processing into Factor VIII and Factor IX concentrates.

Because of the Spectra system's ability to estimate platelet yields before a platelet collection procedure is begun, donor pools can be optimized by collecting double-platelet products from donors with sufficiently high platelet counts and sufficient total blood volumes. This provides the additional advantage of keeping some HLA-matched donors, such as family members of cancer patients, from having to undergo as many apheresis procedures.

For patients undergoing therapeutic procedures, the Spectra system can be used to exchange or deplete blood components. In addition, it can be used for autologous collections of platelets and plasma from patients who will later require transfusion of those blood products.

The Spectra system can be used to perform therapeutic plasma exchange on patients with autoimmune diseases or for patients about to undergo a transplant operation. It can be used to perform red blood cell exchange on patients with hematological disorders such as sickle cell anemia and thalassemia, for which packed red blood cells would typically be used as the replacement fluid, and on patients with polycythemia or hemochromatosis, for which normal saline or albumin would typically be used as the replacement fluid. The system can also be used to perform therapeutic platelet depletions from patients with thrombocytosis.

The Spectra system can also be used for mononuclear and granulocyte (polymorphonuclear) white cell removal.

Spectra platelet collection and plasma exchange procedures can be performed in either the dual-needle mode (one access needle and one return needle) or single-needle mode (one access/return needle). Because of the design of the single-needle procedures, both the extracorporeal volume and process time remain low. In addition, the donor or patient benefits from a single access/return needle site and the apheresis staff benefits from having to perform and manage only one venipuncture.

The Spectra system consists of disposables (preconnected separation channel and blood tubing) and the Spectra Apheresis System itself. The system components include the following:

- Spectra Blood Tubing Sets – Each consists of a separation channel that spins in the centrifuge to separate blood into its components and blood tubing that routes blood and replacement fluids through the system.

- The Spectra Apheresis System – is an automated centrifuge-based blood cell separator that provides the functions necessary to control and monitor the extracorporeal circuit during apheresis procedures.

The system's automated procedures set and maintain the red blood cell/plasma interface for you by defining the pump flow rates, run time, and centrifuge speed. This automation is enhanced by the user-friendly communications display and associated keyboard. The display and keyboard allow two-way communication between you and the system. This ensures complete donor/patient safety and still allows you freedom to control the procedure. Other Spectra ease-of-use features include the following: rapid tubing installation, automatic prime, predictable collection and exchange results, clear alarm information, and automatic rinseback.

Figure 1-1 is an overall exterior view of the Spectra Apheresis System without the disposables or flow path overlay in place.

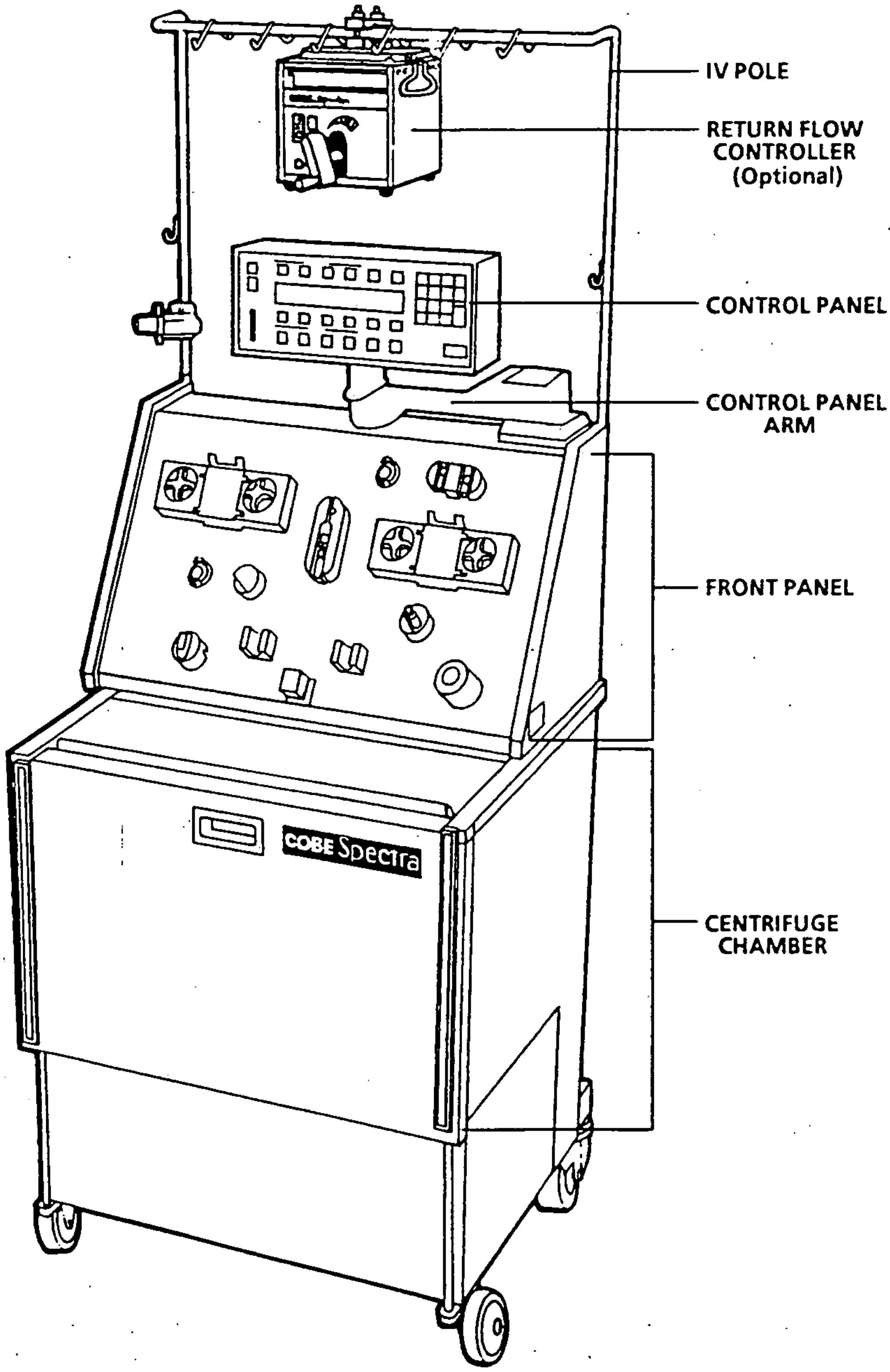

Figure 1-1. Spectra Apheresis System Without Disposables or Flow Path Overlay Attached

DISPOSABLE BLOOD TUBING SETS

Each Spectra blood tubing set is composed of the separation channel and blood tubing that are preconnected for easy installation. Each blood tubing set separates whole blood into its major components: erythrocytes (red cells), leukocytes (white cells), thrombocytes (platelets), and plasma. However, each blood tubing set has a different purpose for separation as follows:

1. **Dual-Needle Extended Life Platelet Set, Catalog Number 777003-000 (ELP™ Set)** – is a functionally closed set used either to collect donor platelets for storage up to 5 days or for therapeutic platelet depletions. If desired, it can also be used to collect plasma concurrently with platelets. This set consists of a dual-stage platelet channel and extended life platelet blood tubing and is for use with dual-needle procedures.

   - **Dual-Stage Platelet Channel** – collects platelets and, if desired, plasma, with low cellular contamination. This is done in two stages: first, it separates platelets and plasma from red and white cells; second, it concentrates platelets by reducing plasma volume.

   - **Extended Life Platelet Tubing** – collects platelets for extended storage and, if desired, plasma through a functionally closed circuit consisting of tubing, access needle, platelet collect bag, plasma collect bag, and filters (sterile barriers used on incoming fluid lines). This tubing set is for dual-needle operations: one donor/patient access point and one donor/patient return connection.

2. **Single-Needle Extended Life Platelet Set, Catalog Number 777003-100 (ELP™ Single-Needle Set)** – is a functionally closed set used to collect platelets for storage up to 5 days. If desired, it can also be used to collect plasma concurrently with platelets. This set consists of a dual-stage platelet channel and extended life platelet blood tubing and is for use with single-needle procedures.

   - **Dual-Stage Platelet Channel** – collects platelets and, if desired, plasma, with low cellular contamination. This is done in two stages: first, it separates platelets and plasma from red cells and white cells; then it concentrates platelets by reducing plasma volume.

   - **Extended-Life Platelet tubing** – collects platelets for extended storage and, if desired, plasma through a functionally closed circuit consisting of tubing, access/return needle, platelet collect bag, plasma collect bag, and filters (sterile barriers used on incoming fluid lines.) This tubing set is for single-needle operations: one access/return donor/patient connection.

3. **Platelet Set, Catalog Number 777004-000 (Platelet Set)** – is used either to collect donor platelets for storage up to 24 hours or for therapeutic platelet depletions. If desired, it can also be used to collect plasma concurrently with platelets. This set, which is not functionally closed, consists of a dual-stage platelet channel and platelet blood tubing. It can be used for either dual-needle or single-needle procedures.

   - **Dual-Stage Platelet Channel** – collects platelets and, if desired, plasma, with low cellular contamination, as described above.

   - **Platelet Tubing** – collects platelets for storage up to 24 hours through a circuit that is not functionally closed. The access needle is not preconnected nor are there sterile barrier filters on incoming fluid lines. This tubing set can be used for either dual-needle or, when used with the Single-Needle Set (see No. 7 below), single-needle procedures.

4. **Therapeutic Plasma Exchange Set, Catalog Number 777005-000 (TPE Set)** – is used to remove plasma from patients requiring therapeutic plasma exchange. This set consists of a single-stage TPE channel and TPE blood tubing. It can be used for either dual-needle or, when used with the Single-Needle Set (see No. 7 below), single-needle procedures.

   - **Single-Stage TPE Channel** – separates plasma from the cellular components.

   - **TPE Tubing** – transports blood for therapeutic plasma exchange procedures.

5. **Red Blood Cell Exchange Set, Catalog Number 777007-000 (RBCX Set)** – is used to remove red blood cells from patients requiring red blood cell exchange or erythrocytapheresis. This set consists of a single-stage RBCX channel and RBCX blood tubing.

   - **Single-Stage RBCX Channel** – separates cellular components from plasma.

   - **RBCX Tubing** – transport blood for red blood cell exchange procedures.

6. **White Blood Cell Set, Catalog Number 777006-000 (WBC Set)** – is used to remove selected populations of white cells from individuals. This set consists of a single-stage WBC channel and WBC blood tubing.

   - **Single-Stage WBC Channel** – separates mononuclear or granulocytes (polymorphonuclear) white cell populations from red cells, platelets, and plasma.

   - **WBC Tubing** – transports blood to remove white cells.

The components of these six Spectra blood tubing sets and the Single-Needle Set are described in greater detail in the following pages.

7. **Single-Needle Set, Catalog Number 777000-100 (Single-Needle Set)** – used to convert dual-needle Platelet and TPE blood tubing sets to single-needle operation.

   - **Single-Needle Bag** – during draw phase of single-needle procedures, holds blood components to be returned to donor/patient during return phase. The bag is placed in the single-needle Return Flow Controller. (See Figure 1-16.)

   - **"Y" Connector** – used to connect access and return lines of dual-needle Platelet and TPE blood tubing sets to one donor/patient access/return needle so these sets can be used during single-needle procedures.

DUAL-STAGE PLATELET CHANNEL (See Figure 1-2)

The dual-stage platelet channel is used for platelet collections and depletions and if desired, concurrent plasma collection. Whole blood enters the first stage of the channel through the inlet tube. In the first stage, the red blood cells (RBC) and white blood cells (WBC) are separated from the platelet-rich plasma. The red cells and white cells exit the channel through the RBC tube (connected upstream to the control tube). Platelet-rich plasma flows over the dam into the second stage. The platelets are concentrated in the plasma by increased centrifugal force in the second stage and exit through the collect tube. The remaining plasma flows around the channel to the plasma tube where the larger volume exits. If a specific volume of plasma is to be concurrently collected, that volume is routed to the plasma collect bag. A small volume of plasma and red cells flows to the control tube to provide the interface control mechanism. Control is maintained by balancing the pressure drops between the RBC and control tubes in conjunction with the density and viscosity of packed red cells and plasma.

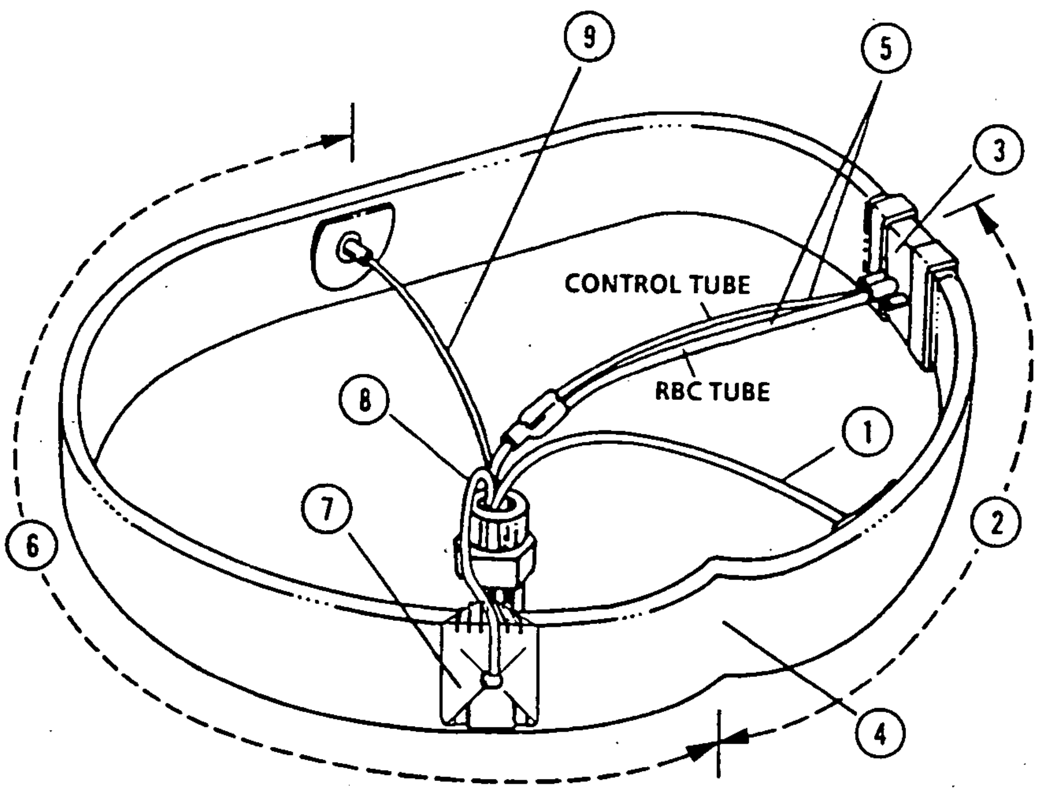

Figure 1-2. Dual-Stage Platelet Channel

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1 **Inlet Tube (red plastic)** – where whole blood enters the channel.

2 **First Stage** – red cells and white cells are separated from platelet-rich plasma in this area of the channel between the control chamber (3) and the second stage (6).

3 **Control Chamber** – maintains the interface between the first and second stages.

4 **Dam** – separation point between the first (2) and second (6) stages.

5 **Two Exit Tubes** – are joined into one tube near the centrifuge collar (see Centrifuge Loop in the **Blood Tubing** description):

a. Red blood cell tube (clear plastic) – with the larger diameter – where red cells and white cells exit the channel for return to donor/patient.

b. Control tube – with the smaller diameter – controls the position of the interface.

6 **Second Stage** – increased centrifugal forces in this area of the channel cause platelets to separate from plasma.

7 **Platelet Collection Chamber** – where platelets are concentrated before exiting the channel.

8 **Collect Tube (clear plastic)** – where platelet concentrate exits the channel for the collect bags.

9 **Plasma Tube (yellow plastic)** – where plasma exits the channel for the plasma bag or to be mixed with red blood cells prior to return to the donor.

SINGLE-STAGE TPE CHANNEL (See Figure 1-3)

The single-stage TPE channel is used for therapeutic plasma exchange procedures. Whole blood enters the inlet chamber through the inlet tube. As it flows through the channel, all the cellular components settle to the outside with the plasma to the inside. Most of the plasma is withdrawn through the plasma out tube, and all the cellular components exit through the RBC return tube. The red cell/plasma interface is maintained in this channel by separating slightly more plasma from the cellular components than is withdrawn through the plasma out tube. The extra plasma then holds the red cell interface out at the RBC return port.

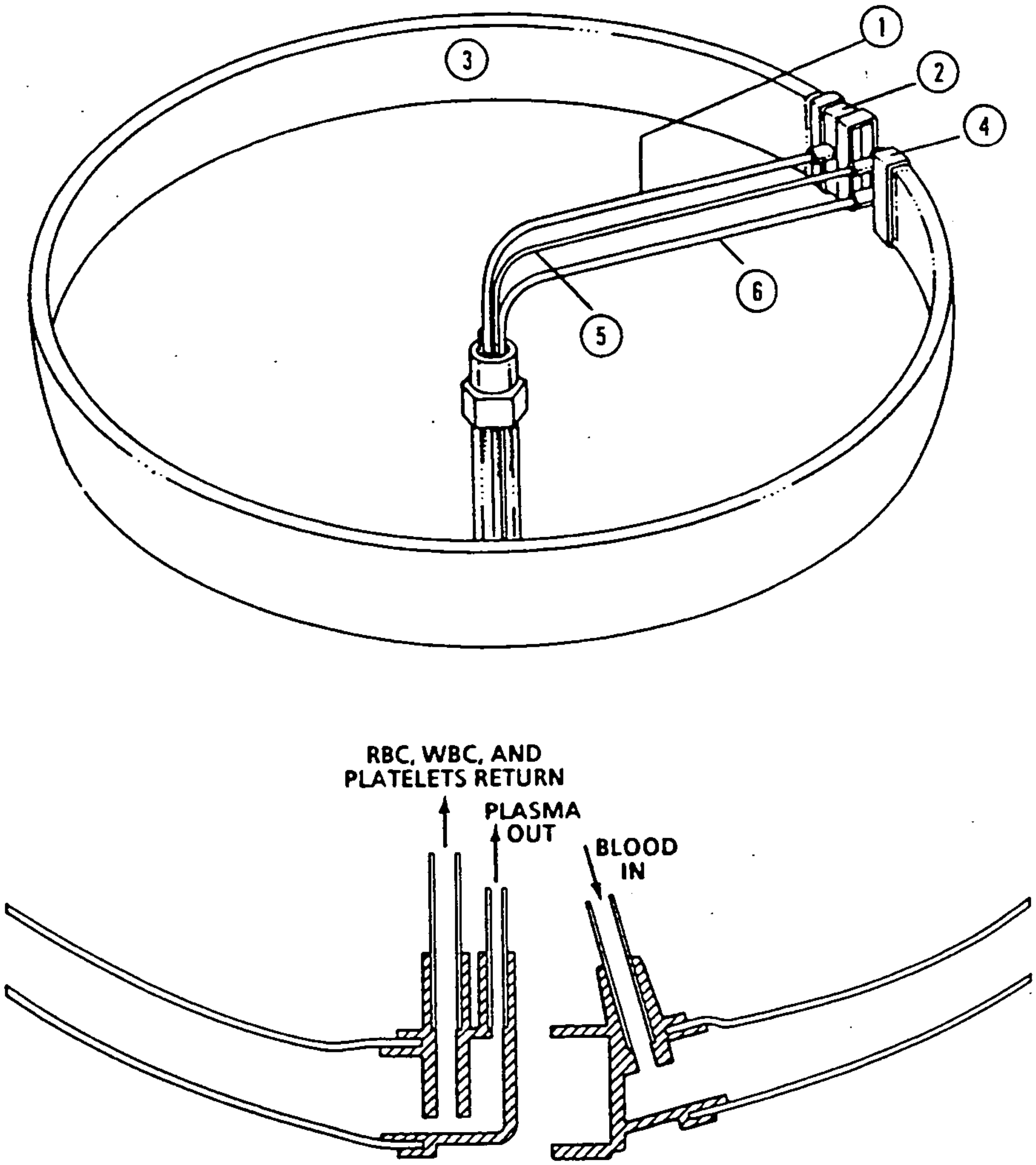


Figure 1-3. Single-Stage TPE Channel

1 **Inlet Tube (red plastic)** – where whole blood enters the inlet chamber (2).

2 **Inlet Chamber** – where whole blood enters the channel (3).

3 **Channel** – where centrifugal force and specific gravity cause plasma to separate from whole blood.

4 **Collection Chamber** – contains the exit tubes (5 and 6).

5 **Plasma Out Tube (yellow plastic)** – where plasma exits the channel for the plasma bag.

6 **RBC Return Tube (clear plastic)** – where cellular components (red cells, white cells, and platelets) exit the channel for return to the patient.

SINGLE-STAGE RBCX CHANNEL (See Figure 1-4)

The single-stage RBCX channel is used for therapeutic red blood cell exchange procedures. Whole blood enters the inlet chamber through the inlet tube. As it flows through the channel, all the cellular components settle to the outside with the plasma to the inside. The red blood cells are withdrawn through the red blood cell out tube, and plasma exits through the plasma return tube. The red cell/plasma interface is maintained in this channel by separating slightly more plasma from the cellular components than is withdrawn through the plasma return tube. The extra plasma then holds the red cell interface out at the red blood cell out port.

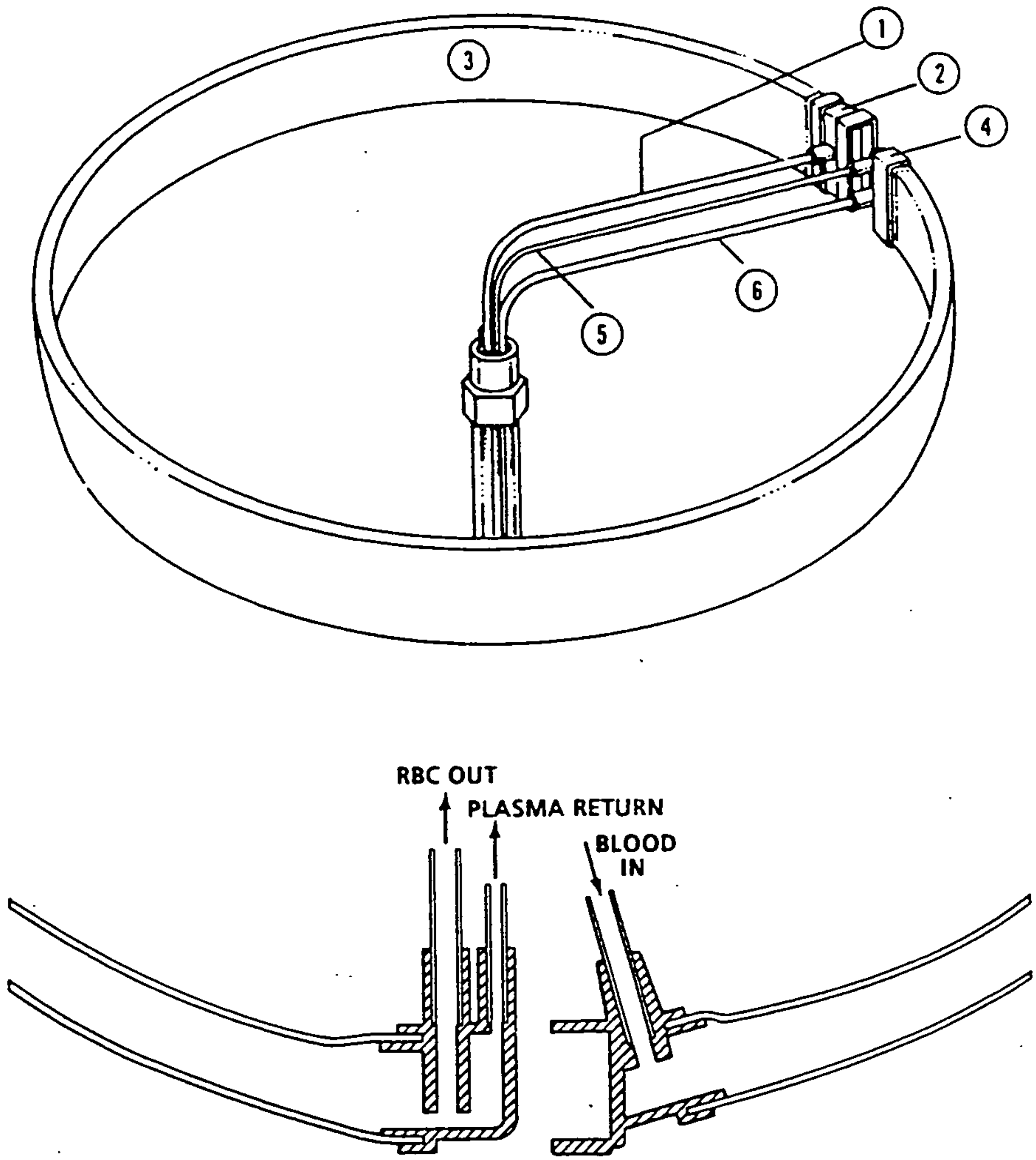


Figure 1-4. Single-Stage RBCX Channel

1 **Inlet Tube (red plastic)** – where whole blood enters the inlet chamber (2).

2 **Inlet Chamber** – where whole blood enters the channel (3).

3 **Channel** – where centrifugal force and specific gravity cause plasma to separate from whole blood.

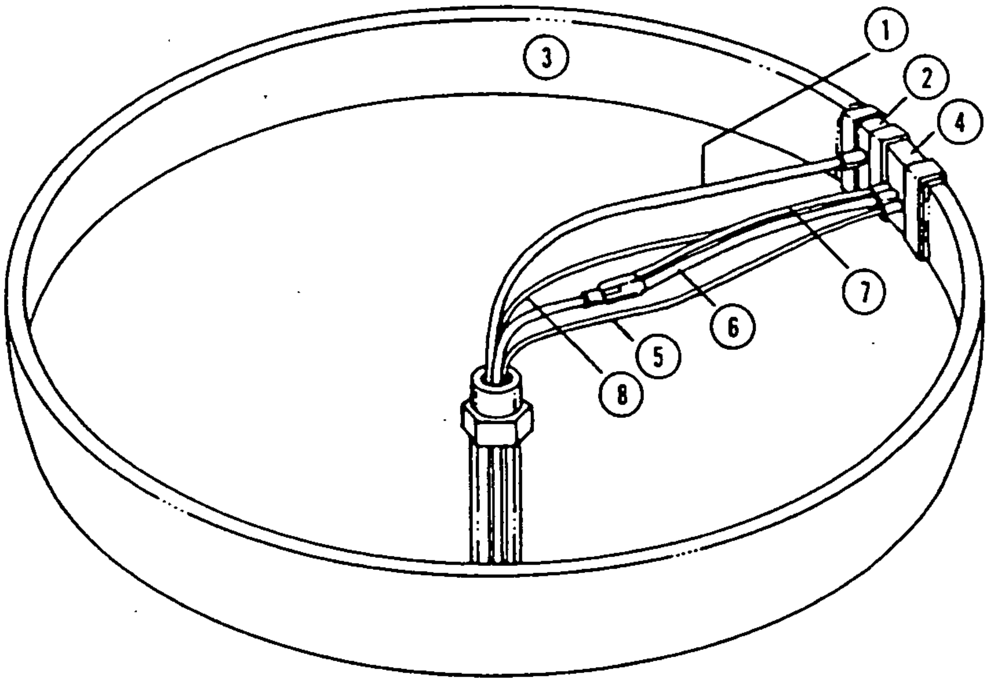
4 **Collection Chamber** – contains the exit tubes (5 and 6).

5 **Plasma Return Tube (yellow plastic)** – where plasma exits the channel for return to the patient.

6 **RBC Out Tube (clear plastic)** – where red blood cells exit the channel for the red blood cell waste bag.

SINGLE STAGE WBC CHANNEL (See Figure 1-5)

The single-stage WBC channel is used for white blood cell (WBC) removals. It can be used to collect either mononuclear cells (MNC) or granulocytes [polymorphonuclear cells (PMN)]. Whole blood enters the inlet chamber through the inlet tube. As it flows through the channel, it is separated into three layers: the red cells are on the outside, the buffy coat containing the selected white cells is in the center, and the platelet-rich plasma is on the inside. The red cell/plasma interface is held in a constant position by balancing the pressure drops in conjunction with the density and viscosity of the red cells and plasma flowing through the RBC and control tubes. The white cells are drawn from the channel through the WBC collect tube while the plasma and platelets exit through the plasma tube.



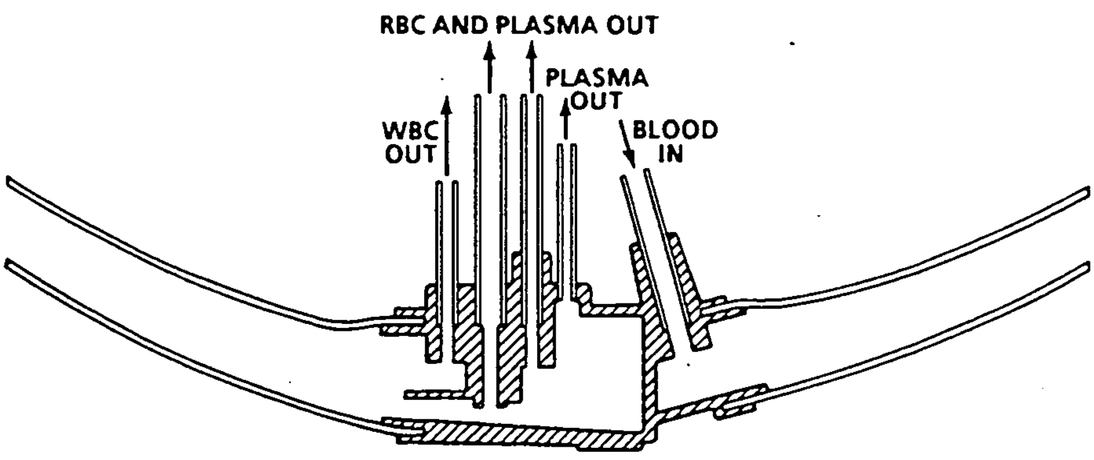


Figure 1-5. Single-Stage WBC Channel

1 **Inlet Tube (red plastic)** – where whole blood enters the inlet chamber (2).

2 **Inlet Chamber** – where whole blood enters the channel (3).

3 **Channel** – where centrifugal force and specific gravity cause whole blood to separate into selected components.

4 **Collection Chamber** – contains the exit tubes (5, 6, 7, and 8).

5 **WBC Collect Tube** – where white cells exit the channel for the collect bag.

6 **RBC Tube (clear plastic)** – with the larger diameter – where red cells exit the channel for return to the subject.

7 **Control Tube (clear plastic)** – with the smaller diameter – maintains the interface in the channel. The RBC and control tubes are joined into one tube near the centrifuge collar (see Centrifuge Loop in the **Blood Tubing** description).

8 **Plasma Tube (yellow plastic)** – where plasma and platelets exit the channel and are mixed with red blood cells prior to return to the subject.

BLOOD TUBING (See Figures 1-6 through 1-11)

1 **Donor/Patient Access**

- Access Needle (ELP) – 17 gauge needle with backeye for donor access.
- Needle Clamp (ELP) – opens and closes the donor access.
- Access Luer (Platelet, TPE, RBCX and WBC) – connects to the donor/patient access needle for dual-needle procedures and to access/return needle for single-needle ELP, Platelet and TPE procedures.
- Access Line Clamp – opens and closes the access line.

2 **Access Manifold** – consists of the access injection site and connections for the access saline line (3), anticoagulant line (4), and inlet line (6). For identification purposes, the three lines are taped together with red tape until they reach the front panel.

3 **Access Saline Line (green-striped)** – carries saline used for priming the extracorporeal circuit and maintaining the donor/patient access when the pumps are turned off.

- Access Saline Filter (ELP) – provides a sterile barrier (5).
- Access Saline Clamp – a roller clamp that opens, closes, or allows a saline drip into the access saline line.
- Access Saline Spike/Drip Chamber – connects to the saline container.

4 **Anticoagulant (AC) Line** – carries anticoagulant.

- AC Filter (ELP) – provides a sterile barrier (5).
- AC Spike/Drip Chamber – connects to the anticoagulant container.

5 **Sterile Barrier Filters (ELP)** – 0.2 micron filters prevent bacteria from entering the system, thereby maintaining a closed, bacteria-free environment for the collection of extended life platelets.

6 **Inlet Line** – carries anticoagulated whole blood to the centrifuge.

7 **Access Pressure Sensor** – attaches to the access pressure sensor housing on the front panel to monitor the donor/patient access blood pressure.

8 **Access Pump Cartridge** – holds and organizes the AC and inlet pump tubing.

9 **Inlet Air Chamber** – provides an inlet filter (200 micron) and air detection chamber.

10 **Centrifuge Loop** – consists of the following:

a. Four-Lumen or Three-Lumen Tubing – carries fluid in and out of the channel.

b. Sleeves – reinforce the tubing at flex points.

c. Collars – fix the two ends of the loop in the centrifuge.

d. Bearings – are contact points between the centrifuge arm and the loop.

11 **Four-Lumen Connector** – provides a tubing-size transition between the centrifuge loop (10) and the front panel lines for ELP, Platelet, and WBC sets.

Three-Lumen TPE Connector – provides a tubing-size transition between the centrifuge loop (10) and the front panel lines for the TPE set.

Three-Lumen RBCX Connector – provides a tubing-size transition between the centrifuge loop (10) and the front panel lines for the R :CX set.

12 **Collect Concentration Monitor Cuvette (ELP and Platelet)** – fits into the collect concentration monitor to measure the concentration of platelets and to detect red cell contamination (over 3% hematocrit) in the collect line (13).

13 **Collect/Replace Line** – carries the collected component to the collect bag (ELP, Platelet, and WBC) or replace solution (TPE and RBCX) to the return line (23) at the return air chamber (20).

- Replace Solution Spikes (TPE and RBCX) – two spikes to connect to the replace solution containers.

- Collect Bag Clamps (Four for ELP; two for Platelet and WBC) – close off the collect bags.

14 **Collect Bag(s)** (1-Liter Bag: two for ELP; one for Platelet and WBC) – where the collected component is stored.

15 **Plasma/RBC Line** – carries plasma for ELP, Platelet, TPE, and WBC procedures and removed red cells for RBCX procedures.

- Plasma/RBC Bag Connector (Platelet, TPE, RBCX, and WBC) – a luer to attach to a plasma or red blood cell bag, if desired.

- Plasma/RBC Line Clamp – closes off the plasma/RBC line.

16 **Plasma/RBC Bag (ELP, TPE, and RBCX)** – for ELP, a 1-liter bag to hold removed concurrently collected plasma; for TPE, a 4-liter waste bag to hold removed plasma; for RBCX, a 4-liter waste bag to hold removed red cells.

17 **RBC/Plasma Line** – carries separated blood components from the channel for return to the donor/patient as follows:

- ELP and Platelet – carries red cells and white cells.

- TPE – carries red cells, white cells, and platelets.

- RBCX – carries plasma.

- WBC – carries red cells.

18 **Return Pump Cartridge** – for ELP, Platelet, and WBC, holds and organizes the plasma and collect pump tubing; for TPE, holds and organizes the plasma and replace pump tubing; for RBCX, holds and organizes the red blood cell and replace pump tubing.

19 **Return Pressure Sensor** – attaches to the return pressure sensor housing on the front panel to monitor the donor/patient return blood pressure.

20 **Return Air Chamber** – provides a return filter (200 micron) and air detection chamber.

21 **Waste Divert Lines** – carry saline and purged air to the waste bag.

22 **Prime Solution Waste Bag** – used at the following times:

- During prime.
- When diverting excess saline during the first portion of a procedure.
- When purging air from the air chambers (9) and (20).

23 **Return Line** – carries blood components returned to the donor/patient.

24 **Return Saline Manifold** – connects the return saline line (25) to the return line (23). For identification purposes, these two lines are taped together with blue tape until they reach the front panel.

25 **Return Saline Line** – carries saline used during prime and to maintain the donor/patient return when the pumps are turned off.

- Return Saline Clamp – a roller clamp that opens, closes, or allows a saline drip into the return saline line.
- Return Saline Spike/Drip Chamber – connects to the saline container.

26 **Donor/Patient Return**

- Return Injection Site – used if an injection is required for the donor/patient.
- Return Clamp – closes off the return to the donor/patient.
- Return Luer – for Dual-Needle ELP, Platelet, TPE, RBCX, and WBC, connects to the donor/patient return needle. For Single-Needle ELP, connects to the single-needle "Y" manifold (28).

27 **Single-Needle Bag** – holds blood components withdrawn from donor/patient during a draw phase of a single-needle procedure until they are returned to the donor/patient during a return phase.

28 **Single-Needle "Y" Manifold** – connects inlet and return lines on a single-needle ELP blood tubing set to a single access/return needle.

29 **Male/Female Luer Lock Connector** – is disconnected and then reconnected to two lines leaving the single-needle bag to connect it to a dual-needle Platelet or TPE blood tubing set to convert that dual-needle set to a single-needle set.

Refer to Table 1-1 for the various blood tubing set configurations.

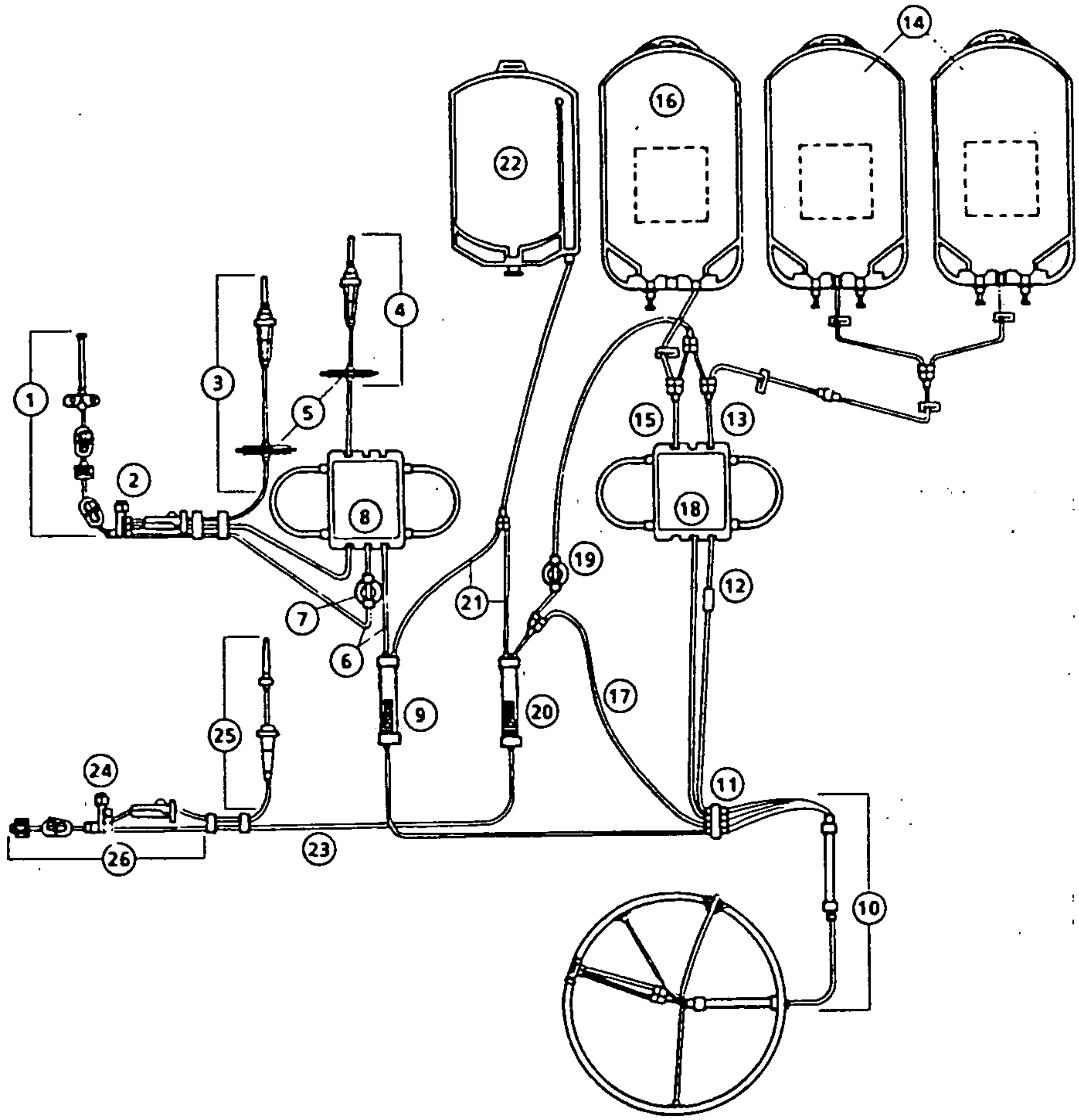


Figure 1-6. Dual-Needle ELP Blood Tubing

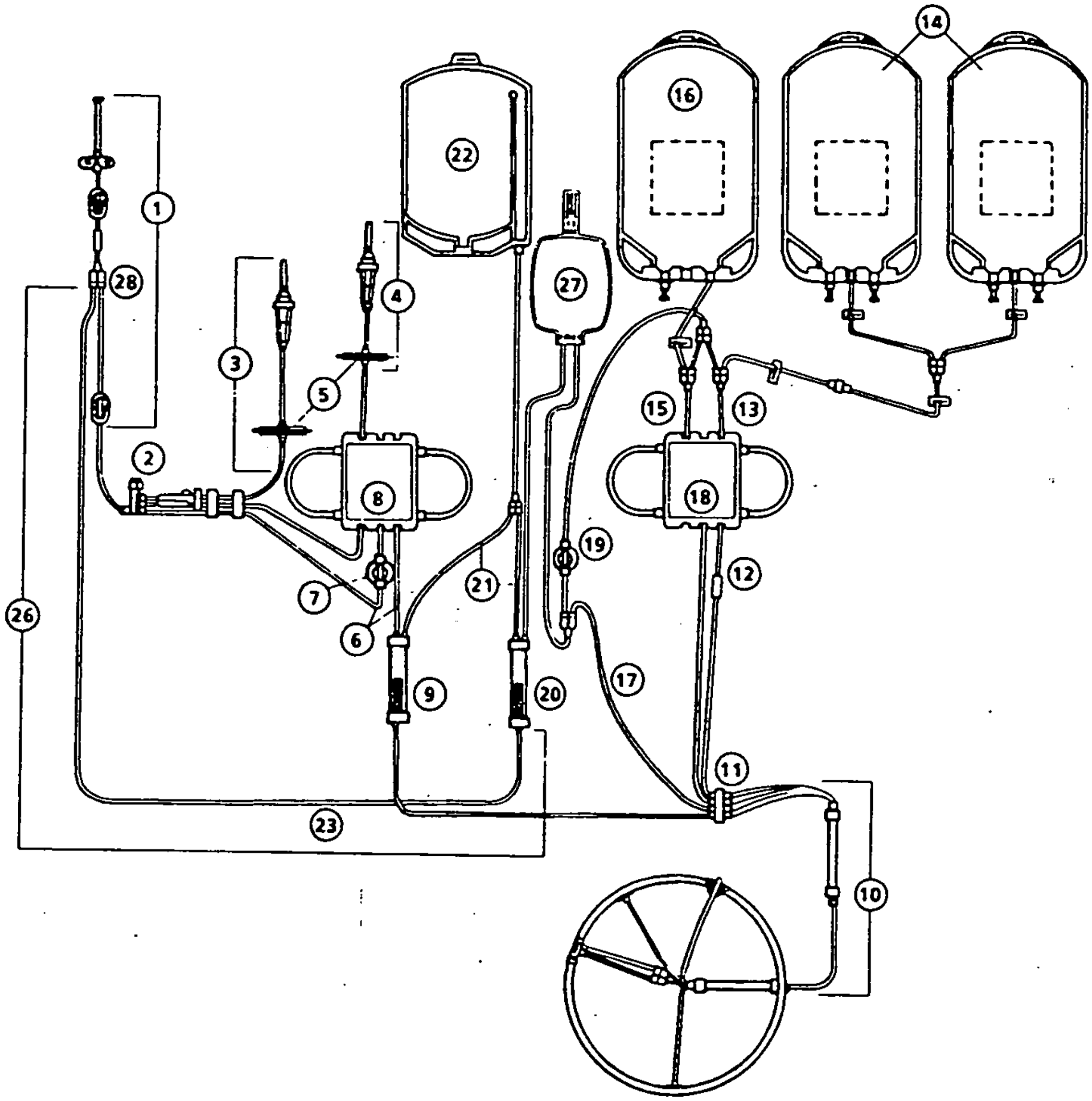


Figure 1-7. Single-Needle ELP Blood Tubing

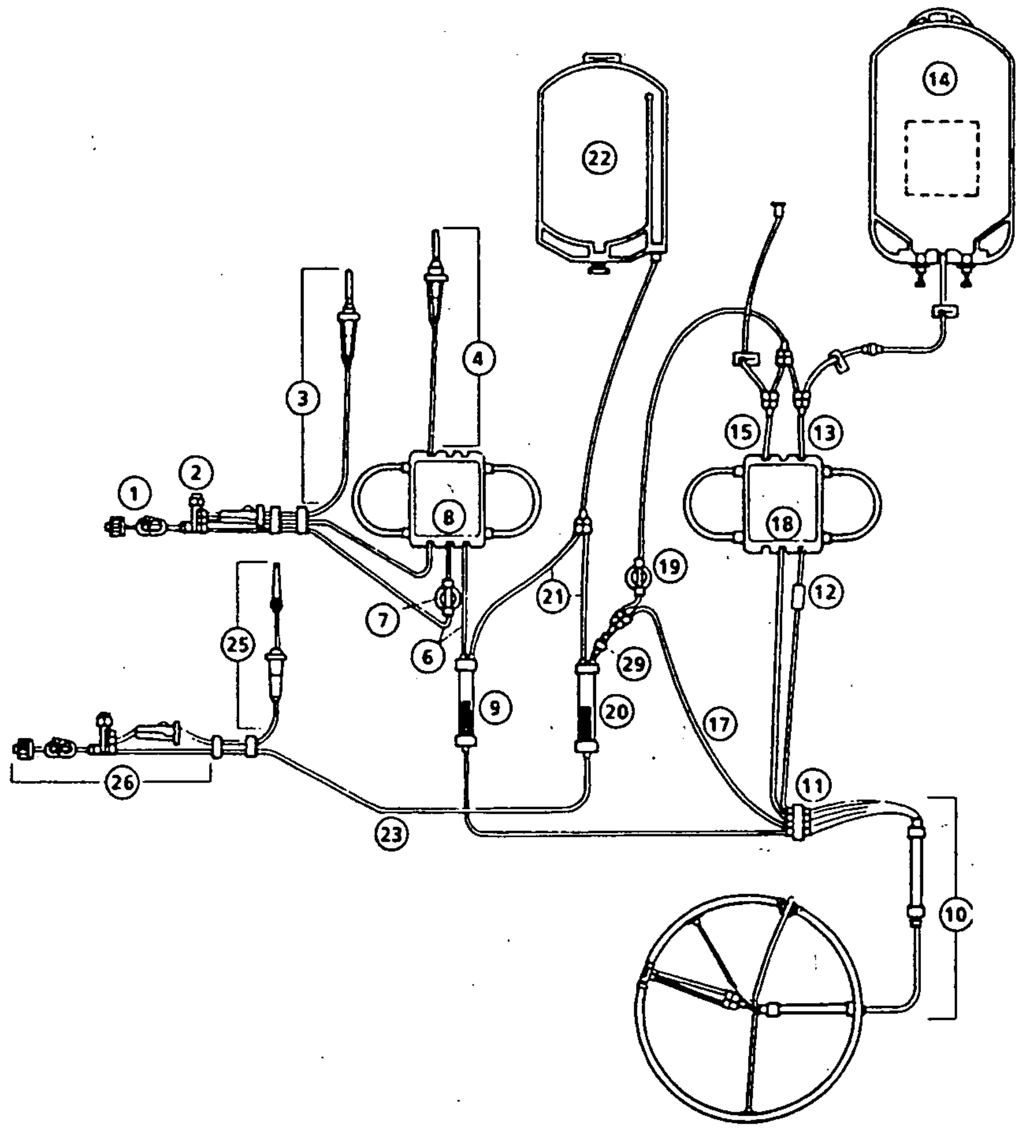


Figure 1-8. Platelet Blood Tubing

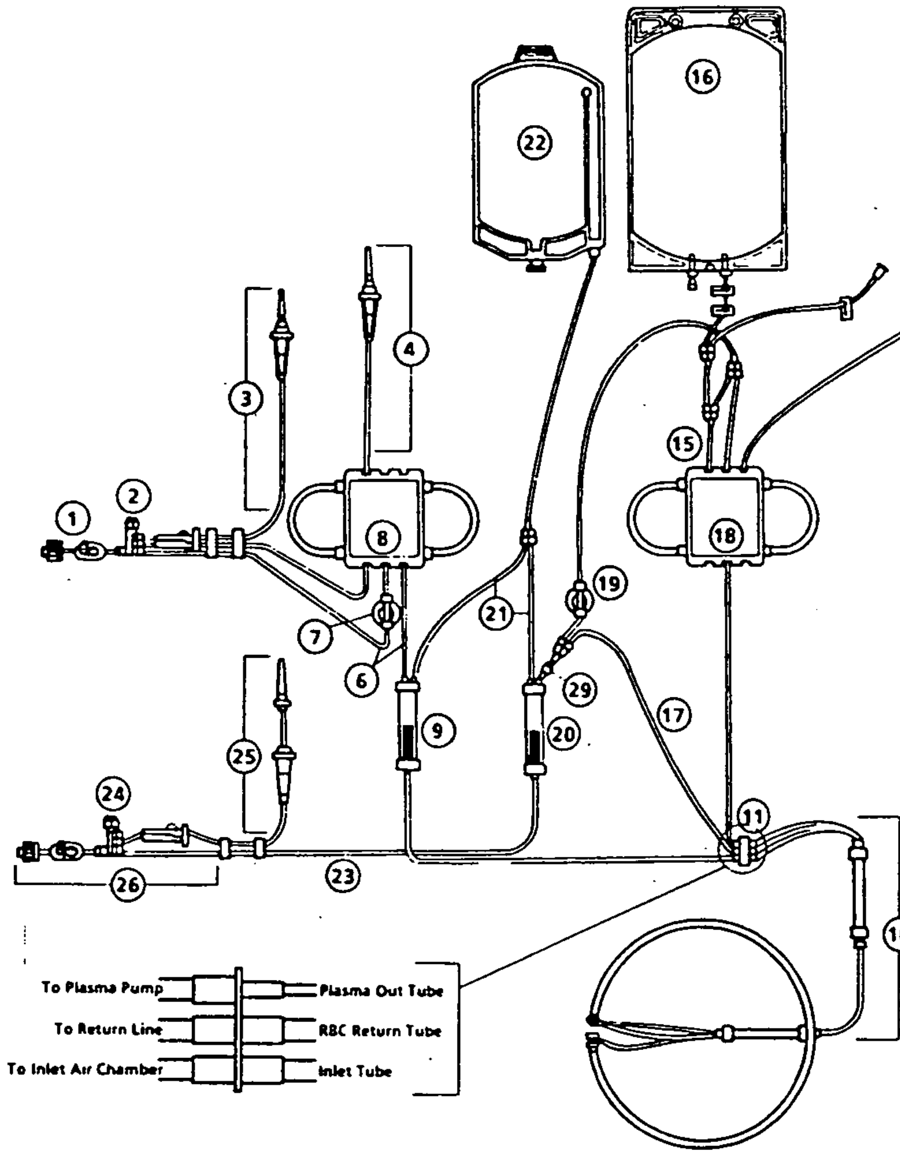


Figure 1-9. TPE Blood Tubing

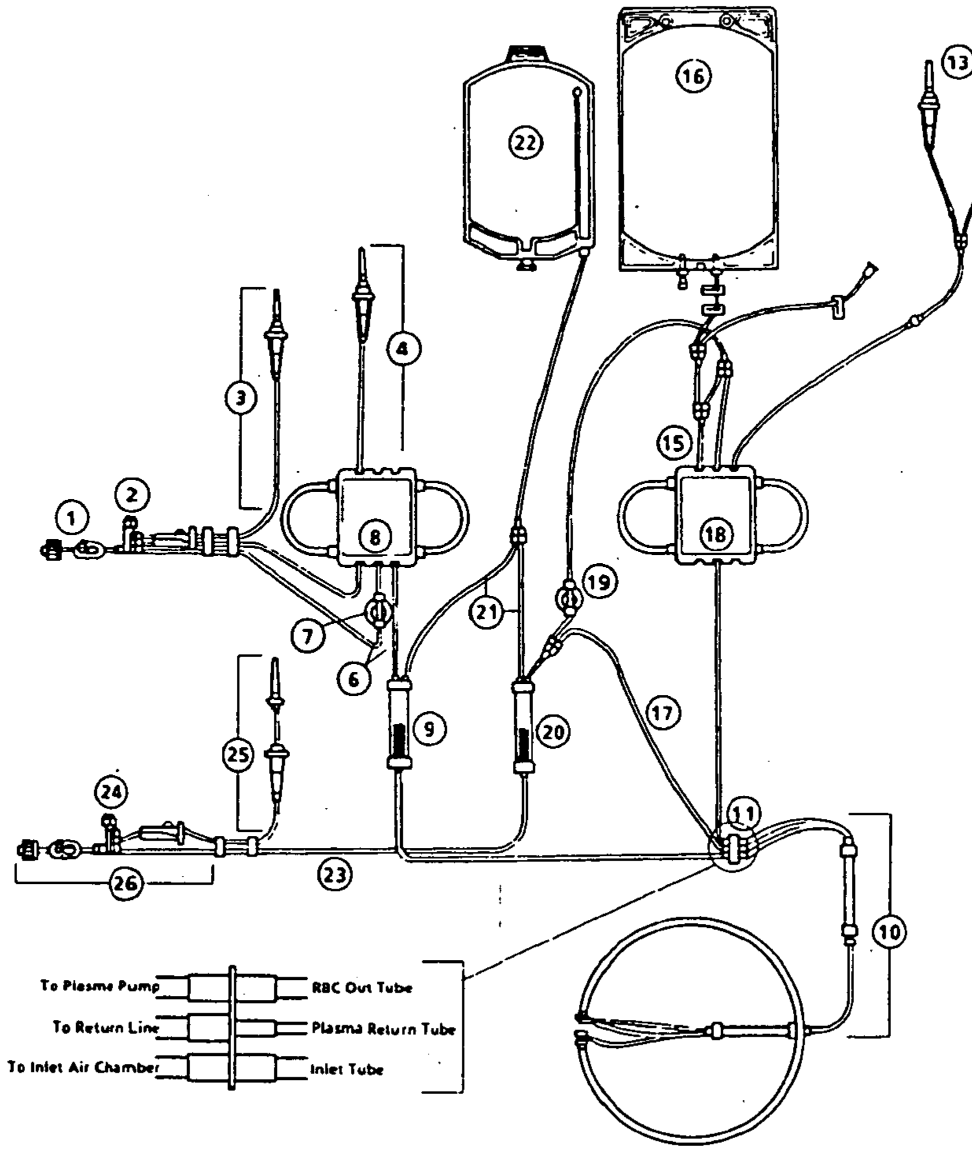


Figure 1-10. RBCX Blood Tubing

CLI 121443

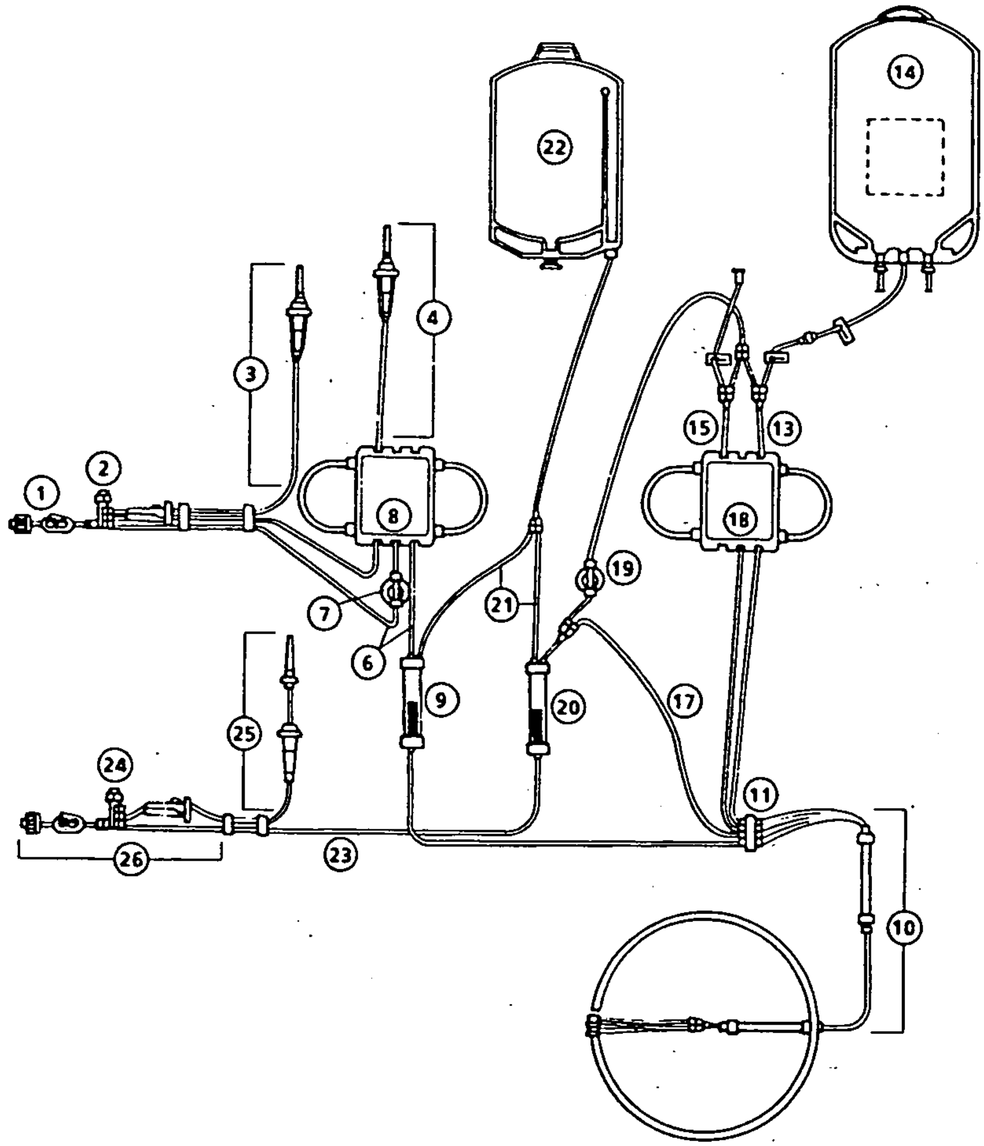


Figure 1-11. WBC Blood Tubing

CLI 121444

Table 1-1. Blood Tubing Set Configurations

Components	Dual-Needle ELP Set	Sng.-Ndl. ELP Set	Plt. Set	TPE Set	RBCX Set	WBC Set
1 Donor/Patient Access	X	X	X	X	X	X
• Access Needle	X	X				
• Needle Clamp	X	X				
• Access Luer	X	X	X	X	X	X
• Access Line Clamp	X	X	X	X	X	X
2 Access Manifold	X	X	X	X	X	X
3 Access Saline Line (Green - Striped)	X	X	X	X	X	X
• Access Saline Filter	X	X				
• Access Saline Clamp	X	X	X	X	X	X
• Access Saline Spike/Drip Chamber	X	X	X	X	X	X
4 Anticoagulant (AC) Line	X	X	X	X	X	X
• AC Filter	X	X				
• AC Spike/Drip Chamber	X	X	X	X	X	X
5 Sterile Barrier Filters	X	X				
6 Inlet Line	X	X	X	X	X	X
7 Access Pressure Sensor	X	X	X	X	X	X
8 Access Pump Cartridge	X	X	X	X	X	X
9 Inlet Air Chamber	X	X	X	X	X	X
10 Centrifuge Loop	X	X	X	X	X	X
• Dual-Stage Platelet Channel	X	X	X			
• Single-Stage TPE Channel				X		
• Single-Stage RBCX Channel					X	
• Single-Stage WBC Channel						X
11 Four-Lumen ELP, Platelet, & WBC Connector	X	X	X			X
• Three-Lumen TPE Connector				X		
• Three-Lumen RBCX Connector					X	

Table 1-1, Cont. Blood Tubing Set Configurations

Components	Dual-Needle ELP Set	Sng.-Ndl. ELP Set	Platelet Set	TPE Set	RBCX Set	WBC Set
12 Collect Concentration Monitor Cuvette	X	X	X			
13 Collect/Replace Line	X	X	X	X	X	X
• Replace Solution Spikes				X	X	
• Collect Bag Clamps	X	X	X			X
14 Collect Bag(s)	X	X	X			X
15 Plasma/RBC Line	X	X	X	X	X	X
• Plasma/RBC Bag Connector			X	X	X	X
• Plasma/RBC Line Clamp	X	X	X	X	X	X
16 Plasma/RBC Waste Bag	X	X		X	X	
17 RBC/Plasma Line	X	X	X	X	X	X
18 Return Pump Cartridge	X	X	X	X	X	X
19 Return Pressure Sensor	X	X	X	X	X	X
20 Return Air Chamber	X	X	X	X	X	X
21 Waste Divert Lines	X	X	X	X	X	X
22 Prime-Solution Waste Bag	X	X	X	X	X	X
23 Return Line	X	X	X	X	X	X
24 Return Saline Manifold	X		X	X	X	X
25 Return Saline Line	X		X	X	X	X
• Return Saline Clamp	X		X	X	X	X
• Return Saline Spike/Drip Chamber	X		X	X	X	X
26 Donor/Patient Return	X	X	X	X	X	X
• Return Injection Site	X		X	X	X	X
• Return Clamp	X		X	X	X	X
• Return Luer	X		X	X	X	X
27 Single-Needle Bag		X				
28 Single-Needle "Y" Manifold		X				
29 Male/Female Luer Lock Connector			X	X		

SINGLE-NEEDLE SET: SINGLE-NEEDLE BAG AND "Y" CONNECTOR (See Figure 1-12)

The single-needle bag and "Y" connector illustrated in Figure 1-12 are used to convert the dual-needle Platelet and TPE blood tubing sets to single-needle operation. The steps for providing this conversion are provided in SECTION 4B - PLATELET SINGLE-NEEDLE OPERATION, SECTION 6B - TPE SINGLE-NEEDLE OPERATION, and SECTION 12 - RECOVERY PROCEDURES.

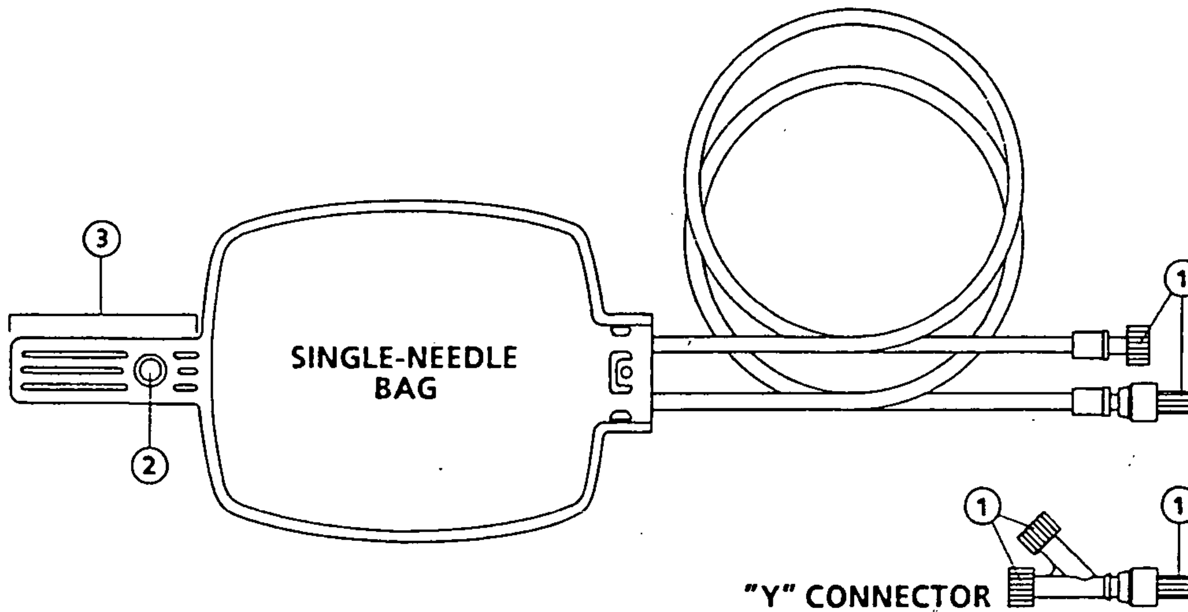


Figure 1-12. Single-Needle Set

1 **Protective Caps**

2 **Locator Hole** on single-needle bag

3 **Load Tab** on single-needle bag

SYSTEM COMPONENTS

For discussion, the Spectra Apheresis System (Figure 1-1) can be divided into three sections: centrifuge chamber, front panel, and control panel. The front of the Spectra system opens to provide access to the centrifuge chamber. Above the centrifuge chamber is the sloping front panel containing the pumps, valves, and sensors used by the system. A swivel arm on top of the Spectra system holds the control panel that includes the keyboard and display screen.

CENTRIFUGE CHAMBER (See Figure 1-13)

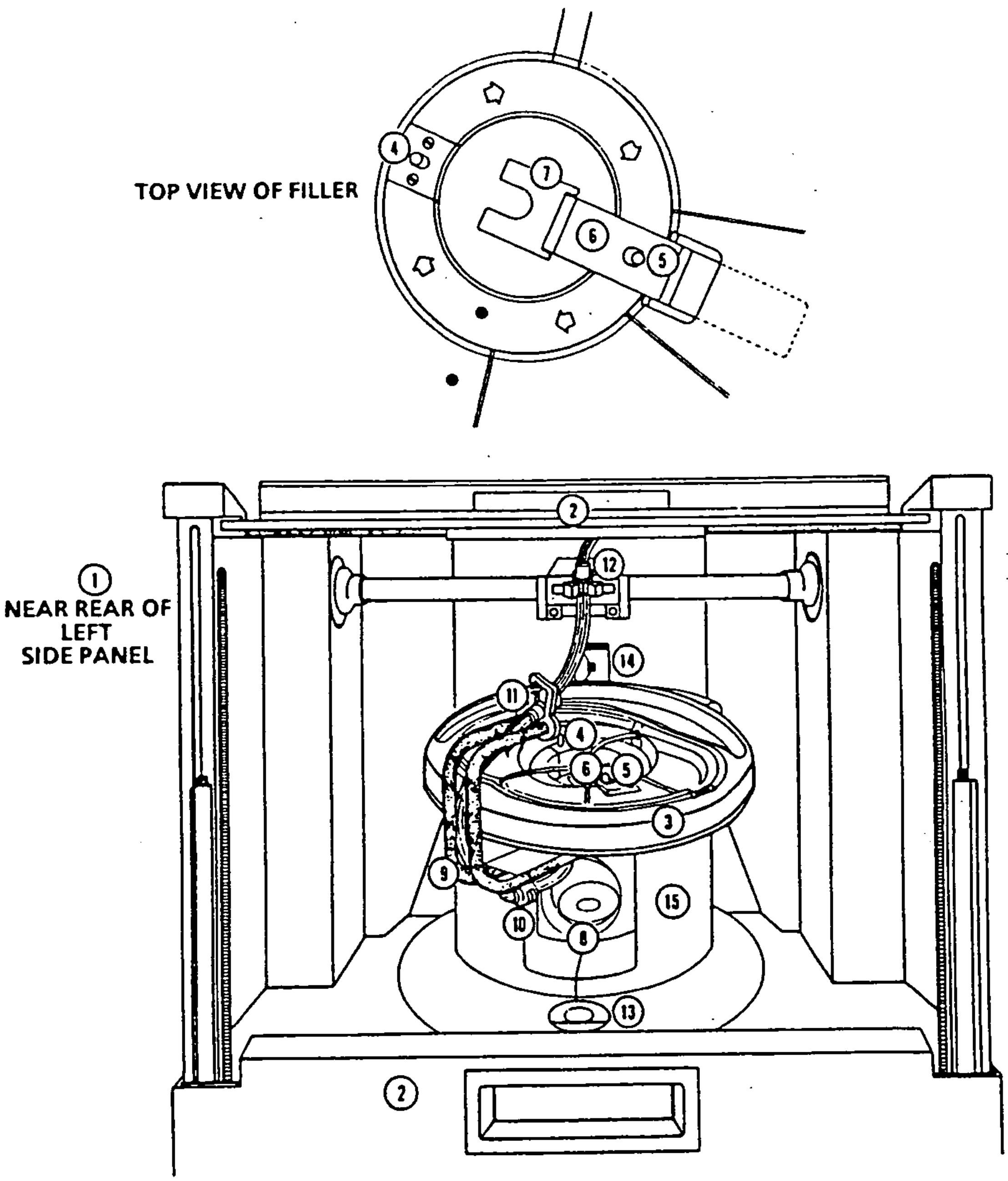


Figure 1-13. Centrifuge Chamber

1 **Power Switch** – turns the power on and off to the Spectra system.

2 **Centrifuge Cover and Door** – allow access to the centrifuge. To protect against excessive light from the strobe (13), the cover is opaque. The view port in the cover is transparent so that you can use the strobe to monitor the separation in the channel. The cover and door are interlocking. To open, turn the power on and press the UNLOCK COVER key on the control panel. Slide the cover back and lower the door. Reverse the order to close and lock the door and cover. To ensure safety, the cover and door will not open when the centrifuge is spinning.

3 **Filler** – holds the separation channel. There are two configurations: one for a dual-stage platelet channel; the other for single-stage channels (WBC and TPE).

4 **Filler Locking Pin** – located on the centrifuge opposite the filler latching pin (5) and filler latch (6) – locks the filler onto the centrifuge.

5 **Filler Latching Pin** – locks the filler latch (6) and, in so doing, locks the filler (3) onto the centrifuge.

6 **Filler Latch** – locks the filler onto the centrifuge. To remove the filler, push the filler latching pin (5) toward the center of the centrifuge and raise the filler latch (6). Then push the filler locking pin (4) toward the center of the centrifuge and raise the filler.

7 **Centrifuge Collar Holder** – located on the end of the filler latch (6) – has a hinged cover to hold one of the nonrotating ends of the centrifuge loop.

8 **Centrifuge Loading Port** – is an opening in the centrifuge housing to enable loading the channel.

9 **Centrifuge Arm** – holds the rotating loop in place as the centrifuge spins.

10 **Lower Bearing Holder** – secures the loop in place on the centrifuge arm (9).

11 **Upper Bearing Holder** – secures the loop in place on the centrifuge arm (9).

12 **Upper Collar Holder** – attaches the upper end of the blood tubing centrifuge loop to the horizontal arm above the centrifuge.

13 **Strobe** – can be turned on to monitor separation in the channel through the centrifuge cover view port (2). Pressing the increase key on the keyboard moves the strobe clockwise, which makes the section of the channel being viewed in the view port appear to move to the right. Pressing the decrease key moves the strobe in the opposite direction.

14 **Fluid Leak Detector** – detects a blood or fluid leak from the channel when the centrifuge is spinning.

15 **Gear Shroud** – protects you from pinch points in the gear train.

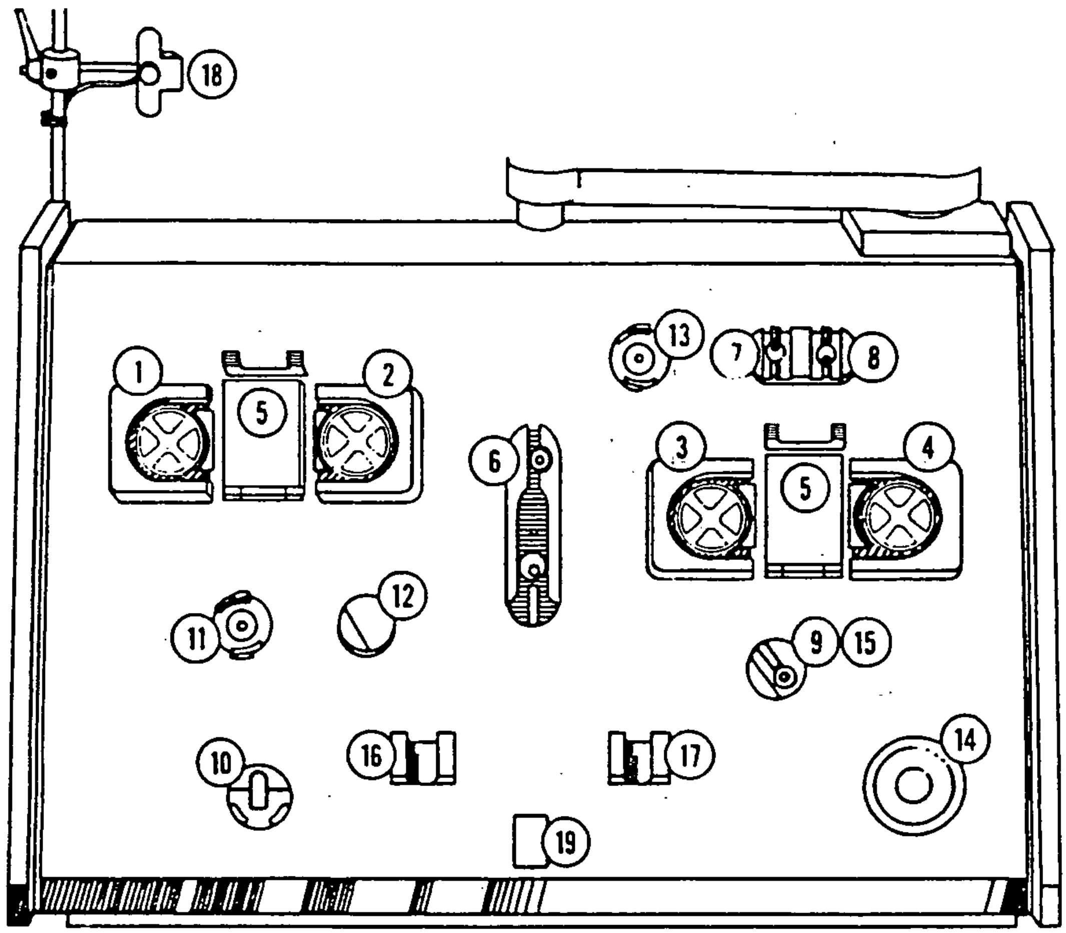


Figure 1-14. Front Panel

Four Pumps – are peristaltic-type with removable rotors for easy cleaning. The pumps are automatically loaded as the pump cartridges are pulled onto the pumps. The action is reversed for automatic unloading.

1 **Anticoagulant (AC) Pump** – pumps anticoagulant from the AC container to the inlet line. For WBC granulocyte (PMN) removal procedures, pumps a prescribed hydroxyethyl starch/sodium citrate solution to the inlet line.

2 **Inlet Pump** – pumps anticoagulated whole blood from the donor/patient access to the centrifuge.

3 **Plasma/Red Blood Cell Pump** – for ELP, Platelet, TPE, and WBC procedures, pumps plasma from the centrifuge to a collect bag (donor or patient) or to recombine with cellular components for return to the donor or patient. For the red blood cell exchange procedure, pumps red blood cells from the centrifuge to the red blood cell collect bag(s).

4 **Collect/Replace Pump** – pumps cells for collection from the centrifuge to the collect bag; or pumps replace solution or red blood cells from the container to the return line.

5 **Cartridge Clamps** – retract to facilitate loading of the pumps. After the pumps are loaded, the clamps hold the pump cartridges in place. To unload the cartridges, unload the pumps and then depress the clamps to release the pump cartridges, which can then be removed and discarded.

Five Valves – four of the five valves are pinch-type where a post rotates onto the tubing to close it and rotates off the tubing to open it. The fifth valve is the return line valve, which is a solenoid, fail-safe clamp that clamps the return line during loss-of-power conditions.

6 **Waste Divert Valve** – consists of one 2-way valve (upper) and one 3-way valve (lower) that operate in conjunction with each other. The valve assembly opens to allow saline to be removed from the centrifuge to the waste bag when a donor/patient procedure begins. It also opens to remove air from the inlet and return air chambers to the waste bag. In addition, the valve is used during the recirculation step of the Rinseback mode. A final position allows tubing to be loaded or unloaded.

7 **Plasma/RBC Valve** – For ELP, Platelet, TPE, and WBC procedures, a 3-way valve that directs plasma flow to a plasma bag or to recombine with cellular components for return to the donor or patient. A third position allows tubing to be loaded or unloaded. For ELP, Platelet, and WBC procedures, the valve can be moved only during Manual operation. Changing from Manual to Automatic operation during WBC procedures moves the valve back to the Return position, allowing plasma to be returned to the subject. For RBCX procedures, the valve that directs red blood cell flow to a red blood cell collect bag.

8 **Collect/Replace Valve** – a 3-way valve that directs flow to the collect bag or, during a red cell spillover, directs flow back to the donor (to protect the platelet product). In a plasma exchange procedure, it allows replace solution to be pumped from the container to recombine with formed elements for return to the patient. A third position allows tubing to be loaded or unloaded. In a red blood cell exchange procedure, it allows the replacement red blood cells to be pumped from the container to recombine with plasma for return to the patient.

9 **Red Blood Cell Line Valve** – a 2-way valve that is in the same housing as the RBC detector (15). This valve closes during the Prime mode to allow air to be pulled out of the channel before it is primed. Also, this valve closes during the Rinseback mode to collapse the channel.

10 **Return Line Valve** – a 2-way valve that closes during a loss of power or some alarm conditions, such as certain system, air, and pressure alarms and any alarm that stops the centrifuge. During single-needle procedures, it also moves to allow for the draw and return phases of each single-needle cycle.

Three Pressure Sensors

11 **Access Pressure Sensor** – a diaphragm-type sensor with a transducer that monitors negative pressure from the donor/patient access site to the inlet pump. This sensor checks for access blood pressure that is too low.

12 **Centrifuge Pressure Sensor** – a strain gauge sensor that measures a force change just following the inlet pump. This sensor checks for centrifuge over pressure (air block or occluded tubing).

13 **Return Pressure Sensor** – a diaphragm-type sensor with a transducer that monitors positive pressure from just prior to the inlet of the return air chamber to the donor/patient return site. This sensor checks for return blood pressure that is too low or too high. During single-needle procedures, this sensor will also measure pressure in the single-needle bag.

Two Concentration Sensors – are optical sensors.

14 **Collect Concentration Monitor** – checks the platelet concentration in the collect line for the following purposes:

- Display the platelet concentration in the collect bag at the end of the procedure.
- Indicate the current platelet yield at any time during the procedure.
- Project the platelet yield for the end of the procedure.
- Detect red cell spillovers greater than 3% hematocrit, and protect the platelet concentration in the collect bag by diverting the red cells back to the donor.

15 **RBC Detector** – located in the same housing as the RBC/Plasma line valve. The sensor detects when red blood cells reach this point (at the beginning of a donor/patient procedure), then closes the waste divert valve and opens the return line valve. The default amounts of inlet volume that will be processed if no red blood cells are detected are based on the inlet volume and tubing set as follows: ELP and Platelet sets = 120 ml; TPE and WBC sets = 150 ml; RBCX set = 0 ml.

Three Air Sensors – are ultrasonic sensors.

16 **Inlet Air Detector** – detects air in the inlet air chamber, stops the pumps to prevent air from entering the centrifuge, and closes the return line valve to prevent air from being returned to the donor/patient.

17 **Return Air Detector** – detects air in the return air chamber, stops the pumps, and closes the return line valve to prevent air from being returned to the donor/patient.

18 **Anticoagulant (AC) Level Detector** – detects when the anticoagulant container is empty. For WBC PMN (granulocyte) removal procedures, detects when the prescribed hydroxyethyl starch (HES)/sodium citrate concentrate container is empty.

19 **Packaging Hook** – holds the package containing the blood tubing set in place on the centrifuge cover for convenience when installing the tubing on the front panel.

Flow Path Overlays – three overlays that name each device on the front panel, helping to ensure correct installation of tubing when setting up disposables.

- Collect Flow Path Overlay – used for collection and depletion procedures.
- TPE Flow Path Overlay – used for therapeutic plasma exchange procedures.
- RBCX flow path overlay – used for therapeutic red blood cell exchange procedures.

CONTROL PANEL (See Figure 1-15)

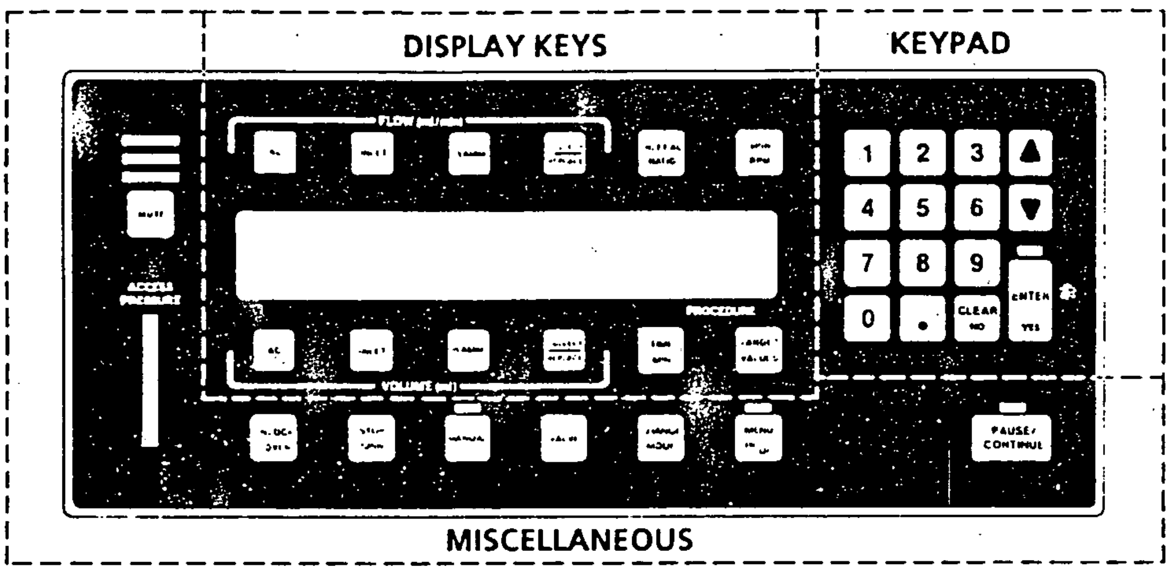


Figure 1-15. Control Panel

Keyboard – keys are grouped into three major functional areas. The numeric keypad is located in the upper right-hand corner. The display keys are the 12 that surround the display screen (6 keys above and 6 keys below). The miscellaneous keys are located on the bottom row and left-hand side. When any key is pressed, it causes a beeping sound. For detailed information on the use of the keyboard, see APPENDIX A – KEYBOARD SELECTIONS.

Keypad

Digit Keys – 0 through 9 are used for entering numeric information and making menu selections.

Increase/Decrease Keys – are multifunctional as described below:

- Upward- and downward-pointing arrows are used to make incremental changes to the numeric value displayed. When an arrow key is pressed and released quickly (within 3/4 second), the numeric value changes a relatively small amount (1-10 units). When an arrow key is held down, after 3/4 second the numeric value starts changing by 10 to 100 units every 1/2 second until the key is released.

- When the keypad is not being used for a numeric entry, the up and down arrows may be used to move the location of the strobe flash on the separation channel. Pressing the up arrow moves the area of the channel displayed by the strobe to the right. Pressing the down arrow moves the area being displayed to the left.

Decimal Point Key – after pressing this key, fraction digits may be entered for a displayed value already showing a decimal point.

CLEAR/NO Key – is multifunctional as described below:

- Numeric Entry – when using the digit keys, the CLEAR/NO key clears the entered digits, restores the displayed value present before the first digit key was pressed, and allows the increase/

decrease keys to be used. When using the increase/decrease keys, the CLEAR/NO key stops or cancels numeric entry.

- YES/NO Questions – when answering YES/NO questions, the CLEAR/NO key indicates a NO answer. This usually causes a screen to be displayed that allows modification of the information that is unacceptable.

- Menu Selection – the CLEAR/NO key is used to back up through menu and patient data screens. If the first level message screen is displayed, the CLEAR/NO key removes the message display and exits the menu system.

- Message Display – The CLEAR/NO key displays the screen messages that are ranked below the current highest-priority screen message.

ENTER LED – is a green LED located over the ENTER/YES key that flashes when you are expected to enter a number, answer a YES/NO question, or make a menu selection (when the ENTER key is a valid choice).

ENTER/YES Key – is multifunctional as described below:

- Numeric Entry – the ENTER/YES key accepts the modified number and completes numeric entry.

- YES/NO Questions – when answering YES/NO questions, the ENTER/YES key indicates a YES answer.

- Menu Selection – the ENTER/YES key makes an explicit menu choice, selects a default choice, leaves the previously selected choice unchanged, or may not be a valid choice.

- Restores Screen Messages – the ENTER/YES key restores the display of higher-priority alarm messages or overridden warnings that have been removed by the CLEAR/NO key.

Display Keys

AC FLOW Key – when pump flow rates are shown on the top line of the display screen, the AC FLOW key allows the AC pump flow rate (in ml per minute) to be changed (in Manual operation only).

INLET FLOW Key – when pump flow rates are shown on the top line of the display screen, the INLET FLOW key allows the inlet pump flow rate (in ml per minute) to be changed.

PLASMA FLOW Key – when pump flow rates are shown on the top line of the display screen, the PLASMA FLOW key allows the plasma pump flow rate (in ml per minute) to be changed (in Manual operation only for ELP, Platelet, and TPE procedures and in Manual and Automatic operation for WBC and RBCX procedures). For RBCX procedures, pressing the PLASMA FLOW key changes the red blood cell flow instead of the plasma flow.

COLLECT/REPLACE FLOW Key – when pump flow rates are shown on the top line of the display screen, the COLLECT/REPLACE key allows the displayed flow rate (in ml per minute) to be changed (in Manual operation only).

INLET:AC RATIO Key – when pump flow rates are shown on the top line of the display screen, the INLET:AC RATIO key allows the ratio of the inlet flow rate to AC flow rate to be changed.

SPIN RPM Key – when pump flow rates are shown on the top line of the display screen, the SPIN RPM key allows the centrifuge speed (in revolutions per minute) to be changed (in Manual operation only).

AC VOLUME Key – the AC VOLUME key serves as a label as follows:

- During Run Mode – AC VOLUME represents the current actual accumulated volume of anticoagulant (in ml) used at any time during the Run portion of the procedure.

- When TARGET VALUES ("Target") Are Displayed – AC VOLUME represents the expected total amount of anticoagulant (in ml) to be used for the procedure.

  For RBCX procedures, the AC VOLUME key is invalid for target values.

INLET VOLUME Key – since inlet volume is used as a limiting factor for ELP, Platelet, TPE, and WBC procedures, the INLET VOLUME key allows the value to be changed as follows:

- During Run Mode – INLET VOLUME represents the current actual accumulated volumes of whole blood and anticoagulant (in ml) that have been processed at any time during the Run portion of the procedure.

- When TARGET VALUES ("Target") Are Displayed – the end-of-run target value is shown and the INLET VOLUME key allows the inlet volume target value (in ml) to be changed.

  For RBCX procedures, the INLET VOLUME key is invalid for target values.

PLASMA VOLUME Key – since plasma volume is used as a limiting factor for therapeutic plasma exchange procedures, the PLASMA VOLUME key allows the value to be changed as follows:

- During Run Mode – PLASMA VOLUME represents (at any time during the Run portion of the procedure) the current actual accumulated volume of plasma and anticoagulant (in ml) collected for either an optional concurrent plasma collection or a therapeutic plasma exchange.

- When TARGET VALUES ("Target") Are Displayed – for therapeutic plasma exchange procedures, the end-of-run target value is shown and the PLASMA VOLUME key allows the plasma volume target value (in ml) to be changed. For optional concurrent plasma collections, PLASMA VOLUME represents the expected total amount of plasma and anticoagulant to be collected.

  For RBCX procedures, the PLASMA VOLUME key is invalid for target values.

COLLECT/REPLACE VOLUME Key – since collect volume is used as a limiting factor for ELP, Platelet, and WBC procedures, and replace volume is used as a limiting factor for therapeutic plasma exchange and red blood cell exchange procedures, the COLLECT/REPLACE VOLUME key allows these values to be changed as follows:

- During Run Mode – COLLECT/REPLACE VOLUME represents (at any time during the Run portion of the procedure) the current actual accumulated volume for one of the following:

  - Amount collected (in ml) for a donor collection or patient depletion.

  - Amount of replace solution (in ml) used during a therapeutic plasma exchange or red blood cell exchange.

- When TARGET VALUES ("Target") Are Displayed – for ELP, Platelet, and WBC procedures, the end-of-run target value is shown and the COLLECT/REPLACE key allows the collect volume target value (in ml) to be changed. For therapeutic plasma exchange and red blood cell exchange procedures, the end-of-run target value is shown and the COLLECT/REPLACE key allows the exchange volume target value (in ml) to be changed.

TIME MIN Key – since run time is used as a limiting factor for a procedure, the TIME MIN key allows the value to be changed as follows:

- During Run Mode – TIME MIN represents the elapsed time of the procedure in minutes.
- When TARGET VALUES ("Target") Are Displayed – the end-of-run time is shown and the TIME MIN key allows the run-time target value to be changed.

  For RBCX procedures, you cannot use the TIME MIN key to change the target value. To change the target time, change the collect/replace volume using the COLLECT/REPLACE VOLUME key.

TARGET VALUES Key – changes back and forth between showing target values and current actual values on the bottom line of the display screen. When showing target values, "Target" is displayed in the bottom right corner. With the exception of the AC volume, the end-of-run target values can be changed by pressing the TARGET VALUES key, selecting the end point to be changed by pressing the appropriate VOLUME key, and entering the new target value. When showing current actual values, one of the following is displayed in the bottom right corner:

- PLTC – Dual-Needle Platelet Collect (Dual-Needle Extended Life Platelet Set or Platelet Set)
- SNPLTC – Single-Needle Platelet Collect (Single-Needle Extended Life Platelet Set or Platelet Set)
- PLTD – Platelet Deplete (Dual-Needle Extended Life Platelet Set or Platelet Set)
- TPE – Dual-Needle Plasma Exchange (TPE Set)
- SNTPE – Single-Needle Plasma Exchange (TPE Set)
- RBCX – Red Cell Exchange (Red Blood Cell Exchange Set)
- MNC – Mononuclear Cell Removal (WBC Set)
- PMN – Polymorphonuclear Cell or Granulocyte Removal (WBC Set)

Miscellaneous Keys

Status Lights (Located Directly Above MUTE Key)

- Safe LED – is a steady green LED that lights to indicate no alarm or warning conditions are present and all alarms are enabled. (All safety systems are activated.) A steady green LED only occurs in Run mode.
- Warning LED – is a yellow LED that flashes to indicate warning conditions. It is a steady light if the warning condition is temporarily overridden or the Spectra system is not in Run mode (some alarms are disabled in Prime and Rinseback modes).
- Alarm LED – is a red LED that flashes to indicate alarm conditions. It is a steady light if the alarm condition is temporarily overridden.

MUTE Key – temporarily silences the error and warning audio alarms. They will stay silent for 60 seconds or until a new, higher-priority alarm occurs.

ACCESS PRESSURE Bar Graph – is a LED bar graph that displays access pressure. There are 18 bars, at 25 mmHg per bar, ranging from 25 mmHg (at the top) to –400 mmHg. The first yellow bar corresponds to the default warning limit (–200 mmHg).

UNLOCK COVER Key – allows the centrifuge cover and door to be opened when the centrifuge is completely stopped. The latches will remain open for 20 seconds – until the centrifuge cover is opened.

STOP SPIN Key – turns off the centrifuge, stops the pumps (puts the Spectra system in Pause with the PAUSE LED flashing), and closes the return line valve once the centrifuge has stopped. Pressing the PAUSE/CONTINUE key restarts the centrifuge and pumps and opens the return line valve. You need to press the PAUSE/CONTINUE key a second time (after seeing the "Centrifuge up to speed. CONTINUE" message) to start the pumps.

MANUAL LED – is a red LED that lights when the Spectra system is performing a procedure in "Manual," overriding the automatic flow rate settings.

MANUAL Key – is only active in the Run mode or while entering donor/patient data after prime is complete. Pressing the MANUAL key while the MANUAL LED is off puts the system in Manual operation, allowing you to control the pump flow rates, centrifuge speed, and valve positions (also lights the MANUAL LED). Pressing the MANUAL key while the MANUAL LED is on returns the system to Automatic operation, letting the algorithms control the pump and centrifuge speeds. (For more details, refer to Appendix C.)

VALVE Key – causes a menu to be displayed, allowing the selection of a particular valve to be moved. The menu will continue to be displayed after a selection has been made so that more valves may be moved. The menu will be displayed for 30 seconds or until the valve key is pressed again or the MENU ON/OFF, CHANGE MODE, ENTER/YES, or CLEAR/NO key is pressed. (For more details, refer to Appendix A.)

CHANGE MODE Key – causes a menu to be displayed, allowing you to choose a different mode of operation. The choices include Load Set, Prime, Run, Rinseback, Unload Set, and Diagnostics. After pressing a valid digit key, the menu is removed and the Spectra system starts the selected mode of operation. If no selection is made, the menu will be removed after 30 seconds. Also, the menu can be removed by pressing the MENU ON/OFF, VALVE, or CLEAR/NO key. (For more details, refer to Appendix A.)

MENU LED – is a green LED located over the MENU ON/OFF key that lights when the menu system is being used.

MENU ON/OFF Key – starts the menu system when the MENU LED is not lit by displaying the first set of choices and lighting the MENU LED. More choices can be viewed by pressing the ENTER/YES key. When a selection is made, the current display is removed (possibly replaced by the next set of choices). If no selection is made, the display will be removed after 30 seconds. Or you can exit the menu system at any point by pressing the MENU ON/OFF key when the MENU LED is lit. The CLEAR/NO key can be used to back out of the menu system one step at a time. The VALVE or CHANGE MODE keys will replace any display with their respective menus. (For more details, refer to Appendix A.)

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PAUSE LED – is a green LED located over the PAUSE/CONTINUE key that lights to indicate that the Spectra system is in a Pause condition (the pumps are stopped). A flashing LED indicates that the pumps can be restarted by pressing the PAUSE/CONTINUE key. A steady LED indicates that an alarm condition must be removed before the pumps can be restarted.

PAUSE/CONTINUE Key – is used in conjunction with the PAUSE LED as follows:

- When the PAUSE LED is off, pressing the PAUSE/CONTINUE key pauses the Spectra system (stopping the pumps and lighting the PAUSE LED). If the pumps are stopped for more than 60 seconds, the centrifuge speed will be limited to 1800 rpm to reduce temperature rise in the centrifuge loop.

- When the PAUSE LED is on and flashing, pressing the PAUSE/CONTINUE key will restart the pumps and turn off the LED. The centrifuge speed will be increased automatically if it has been reduced to 1800 rpm.

- Certain alarm conditions will cause the Spectra system to put itself into Pause. You are prompted to clear the alarm (the PAUSE LED will be on steady, not flashing) before pressing the PAUSE/CONTINUE key.

Display Screen – shows a 2 line by 40 character display. Information displayed on the screen can be grouped into six general categories: 1) state message displays, 2) alarm message displays, 3) operator information displays, 4) VALVE key displays, 5) CHANGE MODE key displays, and 6) MENU ON/OFF key displays.

State Message Displays – show the current state of the Spectra system. (A state is defined as one of possibly many individual steps that the system takes to complete each mode of operation.) The current step the system is performing determines the pump flow rates, centrifuge speed, valve positions, enabled alarms, and display message. The display message either explains what action the system is performing at that time or prompts you to take a specific action or make a selection from a menu. The current mode of operation or an abbreviation of the current procedure appears in the lower right-hand corner. A list of these abbreviations follows the TARGET VALVES key discussion earlier in this section.

Alarm Message Displays – identify the source of an alarm and prompt you as to what action to take to clear the alarm condition. When there is more than one alarm, the highest priority alarm message will be displayed first with an "*" indicator in the lower right-hand corner. This indicates there are more alarms than the one currently being shown. Press the CLEAR/NO key to temporarily view the lower-priority alarm(s). The display of the highest-priority alarm will resume after 30 seconds or if the ENTER/NO key is pressed.

Operator Information Displays – provide you with information and prompts for conditions that do not involve donor/patient safety. Three of the more common information displays (signaled with a long beep) relate to making an inappropriate key selection as follows:

- ___ ___ Key is invalid! – the key selection is not allowed at that particular time (e.g., TARGET VALUES, MANUAL, etc.)

- ___ ___Key – first use MANUAL! – the key selection is allowed only during Manual operation (e.g., AC FLOW, PLASMA FLOW, etc.)

- ___ ___Key – first use TARGET! – the key selection is allowed only when TARGET VALUES are displayed (e.g., INLET VOLUME, TIME MIN, etc.)

VALVE Key Displays – are menus that allow you to move individual valves. The first level menu lets you select the valve to move. The second level menu lets you choose a position to which the valve is to be moved. (See APPENDIX A – KEYBOARD SELECTION for more details.)

CHANGE MODE Key Displays – allow you to put the system in a different mode of operation. (See APPENDIX A – KEYBOARD SELECTIONS for more details.) The modes of operation that can be selected are as follows:

- Load Set
- Prime
- Run
- Rinseback
- Unload Set
- Diagnostics

MENU ON/OFF Key Displays – are menus that allow you to select a number of options. When you make a selection, the display is either removed or replaced by another set of choices. These displays also include donor/patient data questions that determine parameters for donor/patient procedures.

RETURN FLOW CONTROLLER (Figure 1-16)

The COBE Spectra™ Single-Needle Return Flow Controller, Catalog Number 951000-000 – is a Spectra option used only during single-needle ELP and Platelet collections and single-needle TPE procedures. It has two purposes:

- To hold the single-needle bag, which, in turn, holds blood components removed from the donor/patient during the draw phases of a single-needle procedure for return to the donor/patient during the return phases of a single-needle procedure.
- To provide controlled pressure on the single-needle bag to produce the desired return flow during the return phases of a single-needle procedure.

To interpret the meaning of the symbols on the Return Flow Controller's front cover, see Figure 1-17, which is a copy of the permanent label on the Return Flow Controller's back cover. That label provides translations of the meaning of these symbols.

The explanation of the number labels in Figure 1-16 follows:

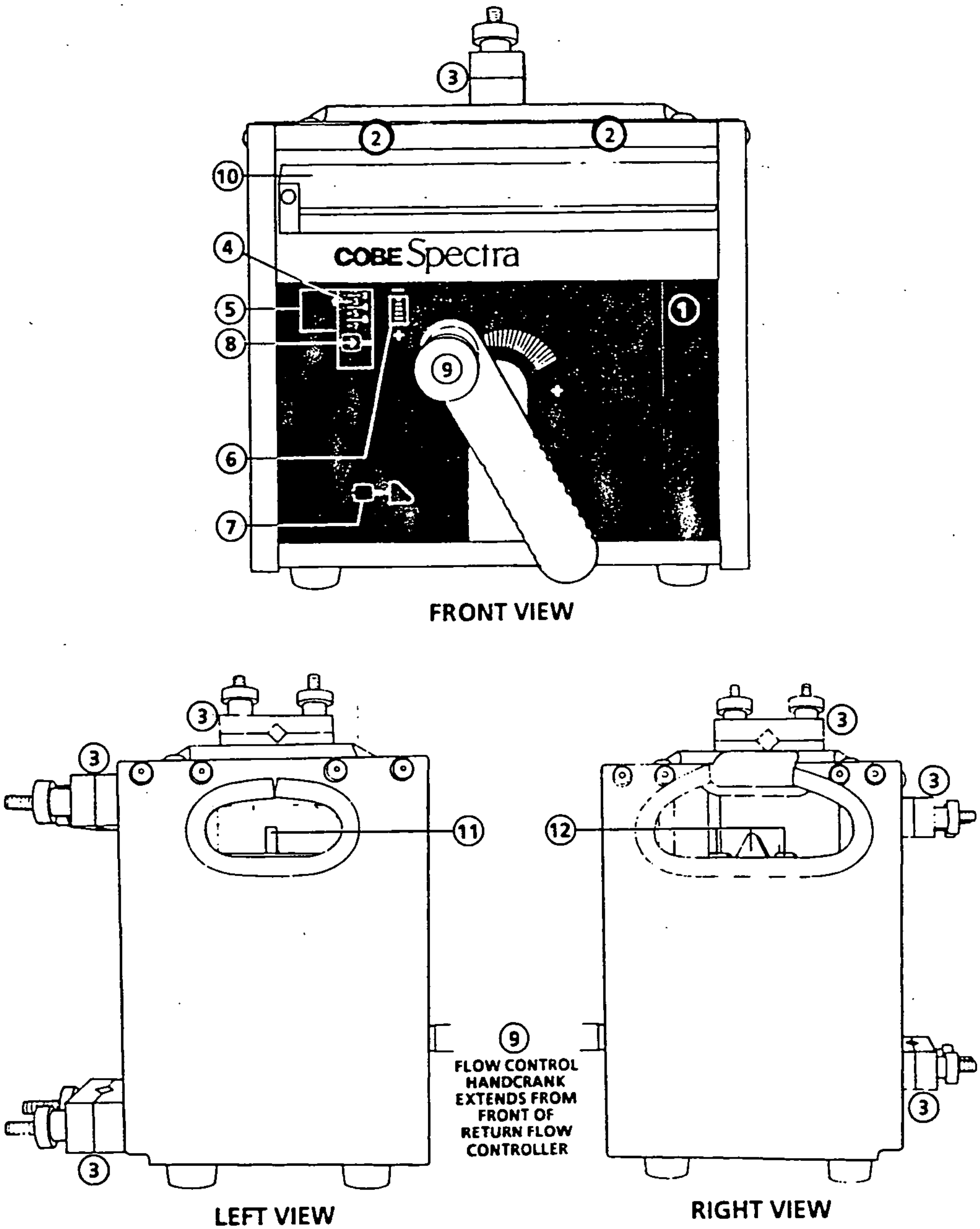


Figure 1-16. Return Flow Controller

1 **Front Cover** – used to keep the Return Flow Controller's internal mechanism clean and graphically illustrate operating modes.

2 **Front Cover Thumb Nuts** – used to remove front cover so the inside of the Return Flow Controller can be cleaned. See **OPERATOR MAINTENANCE OF RETURN FLOW CONTROLLER** section of SECTION 13 – MAINTENANCE for instructions on how to do this.

3 **IV Pole Mounting Clamps** – used to attach the Return Flow Controller to the horizontal or vertical portions of the IV pole. (See Figures 2-3 and 2-4 in SECTION 2 – INSTALLATION.) For instructions on how to install the Return Flow Controller on the IV pole, see **INSTALLATION OF RETURN FLOW CONTROLLER** section of SECTION 2 – INSTALLATION.

4 **Return Flow Indicator** – used to indicate current return flow position on return flow scale **(5)**.

5 **Return Flow Scale** – a numerical scale between 0 and 7 used to set the Return Flow Controller to the appropriate pressure for returning the blood components withdrawn during a single-needle draw phase to the donor/patient. On the scale, 0 (zero) is the "low flow" position and 7 is the maximum flow setting. The correct setting is determined by the inlet flow rate. A display screen message displays the appropriate starting position to which to set the scale. See Figure 1-18 for a detailed view of the return flow scale set to 3.

6 **Return Flow Guide** – helps determine the direction in which to turn the flow controller hand crank (9). As the crank is turned clockwise to increase the return flow rate, the red triangle in the left return flow guide window widens. As the crank is turned counterclockwise to decrease the return flow rate, the red triangle narrows.

7 **Bag Load Indicator** – when the flow control handcrank **(9)** is at the counterclockwise stop, a red arrow appears in the graphic's clear window, indicating that the Return Flow Controller is in the Bag Load position. (See Figure 1-18.)

8 **Prime Mode Position Indicator** – when the flow control handcrank **(9)** is at the clockwise stop, this graphic aligns with the return flow indicator, indicating that the Return Flow Controller is in Prime Mode position. (See Figure 1-18.)

9 **Flow Control Handcrank** – used to place the Return Flow Controller in the Bag Load and Prime Mode positions and to set the return flow rate. (See Figure 1-18.)

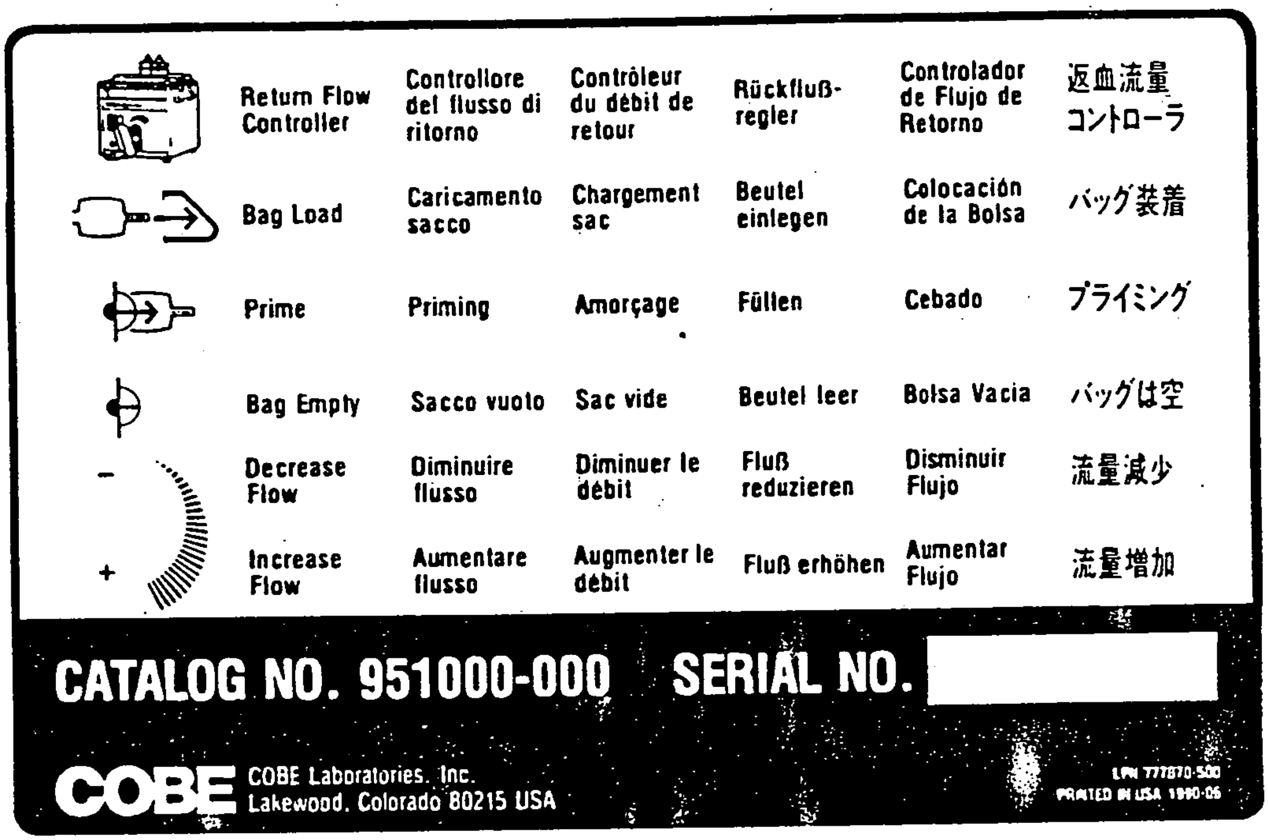
10 **Bag Mounting Plate** – plate in top section of Return Flow Controller on which the single-needle bag lies after it is inserted into the Return Flow Controller.

11 **Bag Locator Pin** – pin on bag mounting plate **(10)** over which the locator hole in the single-needle bag (Figure 1-12) is placed.

12 **Bag Alignment Block** – the two single-needle bag (Figure 1-12) lines are placed on either side of this brass triangle. The single-needle bag is inserted from this side of the Return Flow Controller.

CAUTION

The Single-Needle Return Flow Controller is required to run single-needle procedures. Do not attempt to install (activate) and run a single-needle procedure without a Return Flow Controller and the appropriate disposables.



	Return Flow Controller	Controllore del flusso di ritorno	Contrôleur du débit de retour	Rückflußregler	Controlador de Flujo de Retorno	返血流量コントローラ
	Bag Load	Caricamento sacco	Chargement sac	Beutel einlegen	Colocación de la Bolsa	バッグ装着
	Prime	Priming	Amorçage	Füllen	Cebado	プライミング
	Bag Empty	Sacco vuoto	Sac vide	Beutel leer	Bolsa Vacia	バッグは空
–	Decrease Flow	Diminuire flusso	Diminuer le débit	Fluß reduzieren	Disminuir Flujo	流量減少
+	Increase Flow	Aumentare flusso	Augmenter le débit	Fluß erhöhen	Aumentar Flujo	流量増加

CATALOG NO. 951000-000 SERIAL NO.

COBE

COBE Laboratories, Inc.
Lakewood, Colorado 80215 USA

LPN 777870-500
PRINTED IN USA 1990-05

Figure 1-17. Return Flow Controller Symbol Translation

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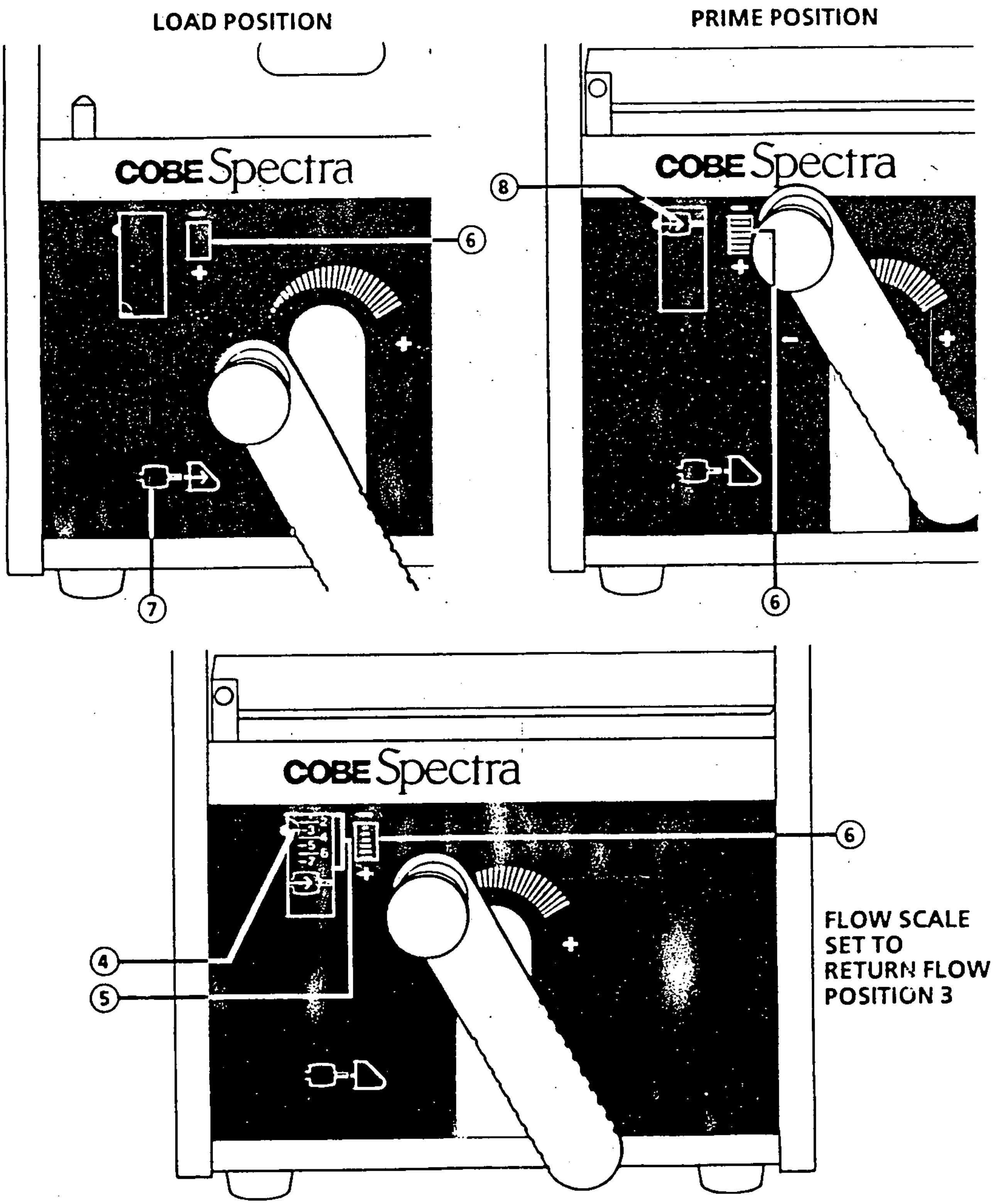


Figure 1-18. Control Indicators on Return Flow Controller

FUNCTIONAL DESCRIPTION

SEPARATION

The Spectra Apheresis System uses a centrifugal method to separate whole blood into its major components: erythrocytes (red cells), leukocytes (white cells), thrombocytes (platelets), and plasma. Whole blood is drawn from a donor or patient, anticoagulated, pumped into the centrifuge, and separated into components. The component removed is collected and the other components are returned to the donor/patient. For therapeutic plasma and red blood cell exchange procedures, appropriate replacement fluid is combined with the returned components.

Anticoagulated whole blood is pumped into the channel while the channel is rotating clockwise in the centrifuge. This causes the component of highest density (red cells) to go to the outer wall of the channel, with layers of components progressing toward the inner wall where the lowest density component (plasma) gravitates. Several outlet tubes are located in the channel. Flow from these tubes collects or returns various components, depending on the procedure performed.

The inlet and collection chambers are separated in the channel. There is one inlet tube that delivers anticoagulated whole blood into the channel. In the TPE and red blood cell exchange (RBCX) channels, there are two tubes for removing components. The tube for removing cellular components extends to the outer wall and the tube for removing plasma is located at the inner wall. However, in a platelet or WBC channel, there are four tubes extending into appropriate areas of the channel. The red cell tube reaches to the outermost wall of the channel, the plasma tube is located at the innermost wall, and the collect and interface control tubes are placed in between where the red cell/plasma interface is located. The interface refers to the thin line (where the separated white cells or platelets are located) between the separated packed red cells and the plasma.

The control tube, along with the relationship between red blood cell and plasma flow rates, establishes and maintains the level of the RBC/plasma interface so that platelets or white cells can be collected at the interface. The relationship between the centrifuge speed and specific gravity of platelets and white cells determines which cell population will collect on the interface. Red cells and plasma can be collected directly from their respective tubes.

FLUID FLOWS

Fluid flows are controlled by the four variable-speed peristaltic pumps on the front panel (Figure 1-14):

- The AC pump controls the flow of anticoagulant into the inlet line.
- The INLET pump controls the flow of whole blood plus anticoagulant from the donor/patient access into the centrifuge.
- The function performed by the PLASMA/RED BLOOD CELL pump depends upon the apheresis procedure in process:
  - For ELP, Platelet, and WBC procedures, it recombines the plasma separated by the centrifuge with cellular components for return to the donor or patient.
  - For TPE procedures and ELP and Platelet procedures involving concurrent plasma collection, it directs the plasma separated by the centrifuge to a plasma collect bag(s) (donor or patient).

- For RBCX procedures, it controls the flow of separated red blood cells, directing them from the centrifuge to a collect bag(s).

- The COLLECT/REPLACE pump controls the flow of components being removed or replaced.
  - For ELP, Platelet, and WBC procedures, it directs the platelets being collected and WBCs being removed to a collect bag(s).
  - For TPE and RBCX procedures, it delivers the appropriate replacement fluid.

For dual-needle procedures, when you use the Spectra keyboard to enter a pump flow rate, you are entering the actual flow rate for that pump for the current procedure. An exception occurs during dual-needle procedures when the high flow configuration is set to "on." During the portion of such dual-needle high-flow procedures when the red blood cell/plasma interface is being established, the inlet flow rate is limited to 45 ml/min. For more information on the high blood flow configuration, see **High Flow Configuration** subsection of the **SETTING CONFIGURATION VALUES** section of this INTRODUCTION.

On the other hand, for single-needle procedures, when you enter a pump flow rate, you are entering the average flow rate for that pump for the current procedure. At any specific instant during a procedure, the instantaneous flow rate for a specific pump can be faster or slower than the average flow rate. Because the pumps do not run at all during the return phase of a single-needle cycle, they must run faster during the draw phase to reach the average pump flow rates you enter.

When you enter a pump flow rate for a single-needle procedure, you may occasionally find that the Spectra system tells you that the flow rate you entered was too high. The system does this by either providing an alarm or lowering the flow rate that you entered. It will not always be obvious why the entered flow rate was too high because the limitations placed on single-needle pump flow rates are more complex than those placed on dual-needle pump flow rates.

For example, for dual-needle procedures, pump flow rates are limited only by the AC infusion rate and donor access characteristics, such as their venous blood flow. For single-needle procedures, the upper limit on pump flow rates may be due to a variety of factors:

- The system limits average inlet flow rates to 50 ml/min for single-needle ELP and Platelet collect procedures and to 60 ml/min for single-needle TPE procedures.

- The Return Flow Controller's 400 mmHg maximum return pressure limits the return flow rate during single-needle procedures.

- The single-needle draw phase's instantaneous inlet flow rate is limited to 150 ml/min.

For more information on single-needle flow control, see the **SINGLE-NEEDLE FLOW CONTROL** section in APPENDIX C – MANUAL AND AUTOMATIC OPERATION.

The upper limits on the average inlet flow rate of 50 ml/min for single-needle ELP and Platelet collection procedures and 60 ml/min for single-needle TPE procedures mean that, under certain circumstances, single-needle procedures can take longer than comparable dual-needle procedures to process the same amount of blood. Up to the single-needle upper limits for average inlet flow rates, single-needle procedures will take approximately 10% to 15% more time to process the same amount of blood.

However, as dual-needle inlet flow rates increase to above the upper limits for single-needle procedures, the comparable single-needle process time will increase additionally based on the following ratio:

$$Q_{in} \text{ (dual needle)}/Q_{in} \text{ (single needle maximum)}$$

For example, if a dual-needle ELP collection procedure were run at an inlet flow rate of 60 ml/min, a comparable single-needle ELP collection procedure would take an additional 20% longer to process the same amount of blood:

$$60/50 = 1.20$$

SYSTEM COMPONENTS

Blood tubing and separation channels form the extracorporeal circuit to and from the donor/patient. The tubing configuration minimizes extracorporeal blood volume which, combined with the channel, holds less than 280 milliliters. During single-needle procedures, the draw cycle can add up to 100 milliliter maximum to the extracorporeal volume. The blood tubing is arranged on the front panel of the Spectra Apheresis System. The channels are placed in the centrifuge chamber. The Spectra system is designed to perform various procedures by utilizing different tubing sets.

In addition to housing the four pumps, which control fluid flow,the front panel also contains valves and sensors. (See Figure 1-14.) There are five valves:

- The WASTE/DIVERT valve is a pinch-type valve that
  - Passes air from the air chambers into the waste bag.
  - Allows the air chambers to be automatically primed.
  - Diverts prime saline to the waste bag at the beginning of a procedure.
- The PLASMA/RBC valve is a pinch-type valve.
  - For ELP, Platelet, and WBC procedures, its Return position recombines the plasma flow with cellular components for return to the donor or patient.
  - For TPE and ELP and Platelet procedures involving concurrent plasma collection, its Collect position directs the plasma flow to a plasma collect bag(s).
  - For RBCX procedures, its Collect position directs the red blood cell flow to a red blood cell collect bag(s).
- The COLLECT/REPLACE valve is a pinch-type valve.
  - Its Collect position is used for cell collection during ELP, Platelet, and WBC procedures.
  - Its Return position is used to return red blood cells back to the donor when a red cell spillover occurs during an ELP or Platelet collection procedure, which protects the platelet product from red blood cell contamination.
  - Its Open/Load position allows the Spectra system to deliver appropriate replacement fluid during TPE and RBCX procedures.

- The RBC LINE valve is a pinch-type valve in the same housing as the RBC detector. It closes during Prime to allow air to be pulled out of the channel and closes during the Rinseback mode to collapse the channel.

- The RETURN LINE valve is a solenoid, fail-safe clamp that
  - Closes if air is detected in the return air chamber.
  - Closes during power interruptions and some other alarm conditions.
  - Closes during the draw phase and opens during the return phase of each single-needle cycle.

The Spectra system has six safety sensors on its front panel:

- The ACCESS and RETURN PRESSURE sensors are diaphragm-type sensors that monitor pressure and turn off the pumps if the pressure exceeds safety limits. During single-needle procedures, the RETURN PRESSURE sensor also measures the pressure in the single-needle bag.

- The INLET and RETURN AIR detectors stop the pumps and close the RETURN LINE valve when they detect air in the inlet or return air chamber.

- The RBC detector is located in the same housing as the RBC LINE valve. It determines when blood has replaced saline at the beginning of a procedure and stops the diversion of inlet flow to the waste bag so that blood components are not lost. If more than 120 milliliters of inlet volume for dual-stage channel procedures (ELP and Platelet procedures) or 150 milliliters of inlet volume for single-stage procedures (TPE and WBC procedures) have been processed, the RBC detector will be overridden. Then the WASTE/DIVERT valve will automatically close and the RETURN LINE valve will automatically open. The RBC detector is inactive during RBCX procedures.

- The AC LEVEL detector is located on the left vertical segment of the IV pole. It triggers an operator warning when the anticoagulant container becomes empty.

  A control panel (Figure 1-15) is attached to the top of the Spectra front panel. (See Figure 1-1.) It consists of a keyboard and display screen, which are an integral part of the Spectra alarm system. The following alarm indicators, located on the control panel, alert you when an alarm condition occurs:

  - Red alarm or yellow warning LED flashes.
  - Audio alarm sounds.
  - Alarm message displays on the screen.

  When an alarm condition occurs, the system automatically stops its pumps (Pauses the system) and, if necessary, stops the centrifuge or closes the return line valve. Less severe conditions (warnings) do not cause the system to shut down. For additional information on the Spectra alarms and warnings, the conditions that may have caused them, and how to troubleshoot/remove those conditions, see SECTION 11 – TROUBLESHOOTING.

In addition to giving alarm information, the screen displays messages that prompt you to input donor/patient data. The microprocessor utilizes this input to calculate the flow and speed parameters that will automatically control separation. Information on flow rates, centrifuge speed, volumes processed, and procedure time appears on the display screen. The display keys and miscellaneous keys are used to adjust parameters and define steps in the procedure for Manual operation. See APPENDIX A - KEYBOARD SELECTIONS and APPENDIX B - DATA INPUT LIMITS for additional information.

AUTOMATIC AND MANUAL OPERATION

The Spectra Apheresis System is capable of operating under Automatic or Manual control. Typical operation is in the Automatic mode where initial values of pump and centrifuge speed are defined automatically to separate components. In this mode, you have the opportunity to adjust the inlet pump flow rate while automatically maintaining the dilution ratio (whole blood plus anticoagulant to anticoagulant); proper plasma, collect, and replace flow rates; and correct centrifuge speed. It is always possible to override the Automatic control. Under the Manual mode, all flow rates and speeds (including anticoagulant and centrifuge) are adjustable. For additional information on the Automatic and Manual modes of operation, see APPENDIX C - MANUAL AND AUTOMATIC OPERATION.

ANTICOAGULATION

BACKGROUND

Anticoagulation is necessary to prevent coagulation in the extracorporeal circuit. It also establishes a pH and ionized calcium environment that prevents cell clumping during ELP and Platelet collection procedures.

ACD-A is the approved anticoagulant for the COBE Spectra Apheresis System for ELP and Platelet collection procedures and the preferred anticoagulant for therapeutic plasma exchange, red blood cell exchange, and WBC removal procedures. A suggested procedure when heparin must be used in anticoagulation for therapeutic plasma exchange is provided in SECTION 10 - HELPFUL HINTS. For granulocyte (PMN) removal, hydroxyethyl starch/sodium citrate concentrate may be used as the anticoagulant where permitted.

The Spectra system controls the AC pump flow rate in order to establish the rate at which anticoagulant returns to the donor or patient. The incidence of symptomatic hypocalcemia is related to the flow rate of ACD-A as well as the donor's or patient's "size" or, more correctly, total blood volume. Therefore, the Spectra system asks for information about the donor's or patient's sex, height, and weight to determine the total blood volume, which is the unit of measure used by the Spectra system for the donor's/patient's "size." Using the configured rate of ACD-A infusion (ml of AC/min/liter of total blood volume) to the donor or patient, the Spectra system then calculates the amount of anticoagulant removed with the plasma and sets the ACD-A pump flow rate appropriately for the size of the donor or patient.

The AC infusion rate is based upon the concept that a donor's or patient's ability to metabolize ACD-A is directly related to that individual's total blood volume. Therefore, the COBE Spectra Apheresis System maintains a constant infusion rate of anticoagulant per minute per liter of total blood volume. Refer to Figure 1-19 to see the relationships between donor/patient variables and other variables such as AC pump flow rate, AC infusion rate, AC infusion rate configuration, inlet:AC ratio, and inlet flow rate.

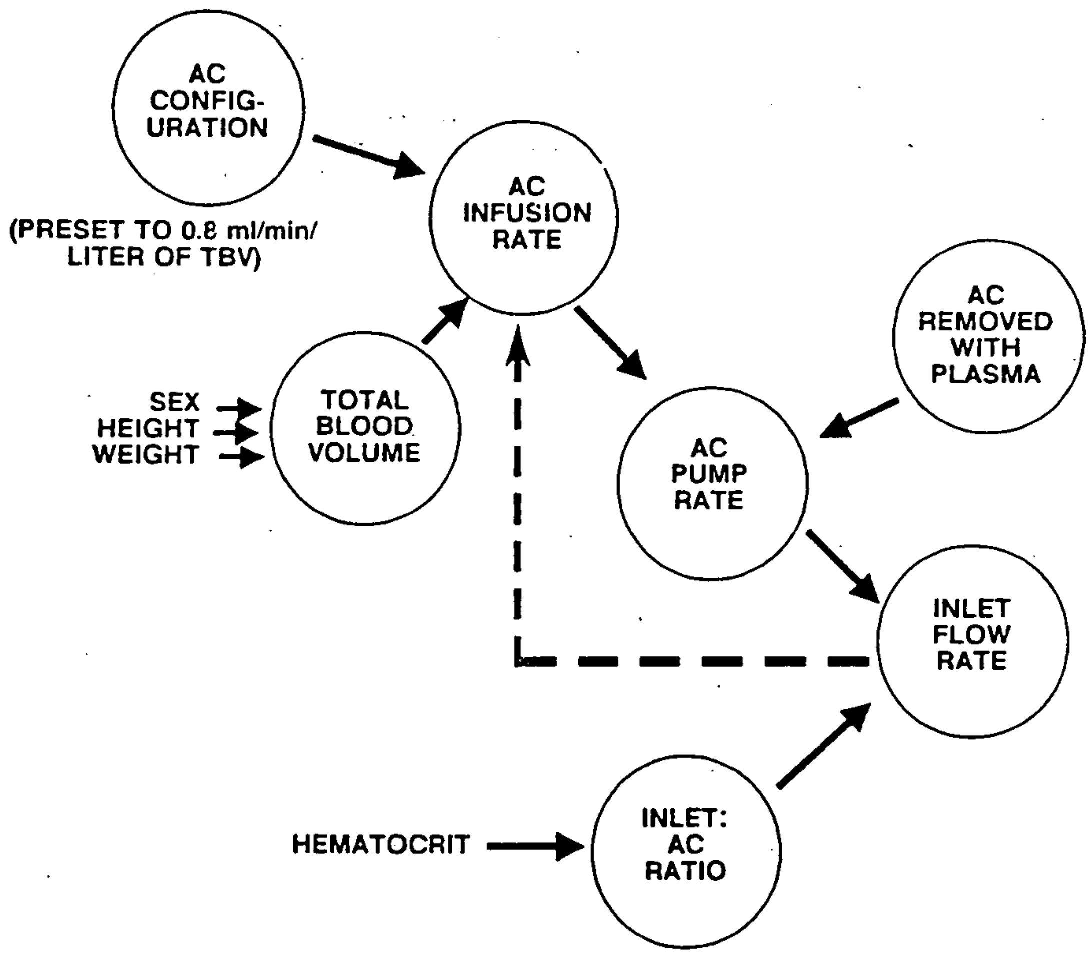


Figure 1-19. Donor/Patient Data Calculations

As indicated in Figure 1-19, the Spectra system first calculates the total blood volume based upon the sex, height, and weight entered as donor or patient data. The AC infusion rate to the donor or patient is then calculated using the total blood volume and the AC infusion rate configuration value that has been programmed into the system. The default value for the AC infusion rate configuration is 0.8 ml/min/liter of TBV. At the direction of the medical di ector, the AC infusion rate configuration can be changed to a value between 0.8 and 1.1 ml/min/liter of TBV. For additional information on the AC infusion rate configuration, see the **AC Infusion Rate Configuration** subsection of the **SETTING CONFIGURATION VALUES** section later in this INTRODUCTION.

For example:

Total Blood Volume X AC Configuration = AC Infusion Rate

5 liters X 0.8 ml/min/liter TBV = 4.0 ml/min

Any direct changes you make to the inlet flow rate change the AC infusion rate. By increasing the inlet flow rate, you can increase the AC infusion rate to 1.2 ml/min/liter of TBV. If you increase the inlet flow rate to the point that the AC infusion rate exceeds 1.2 ml/min/liter of TBV, the "AC infusion rate exceeds allowable limits" alarm occurs. See SECTION 11 – TROUBLESHOOTING for details on that alarm.

To deliver anticoagulant at the rate initially prescribed, as in the example above, the the Spectra system calculates the amount of anticoagulant removed with the plasma in the collection bags. The AC pump flow rate is set so that the amount of anticoagulant removed to the collection bags subtracted from the AC pump flow rate is the AC infusion rate to the donor or patient.

In ELP and Platelet collection procedures, the Spectra system then calculates an AC ratio to

- Keep the blood from clotting during separation and collection
- Establish a pH and ionized calcium environment that keeps the platelets from clumping
- Establish the initial pH necessary for appropriate extended life storage of platelets

In ELP and Platelet collection procedures, the donor's hematocrit is used to calculate the inlet:AC ratio, which is the ratio between inlet flow rate and AC flow rate. The AC ratio varies with the hematocrit because the pH buffering capabilities of the blood in an extracorporeal circuit is directly related to the blood's hematocrit.

(NOTE: For ELP and Platelet collection procedures, the inlet:AC ratio configuration can be changed at the request of the medical director. Refer to the **AC Ratio Configuration** subsection of the **SETTING CONFIGURATION VALUES** section later in this INTRODUCTION. All other Spectra procedures have a default inlet:AC ratio that remains the same for each procedure.)

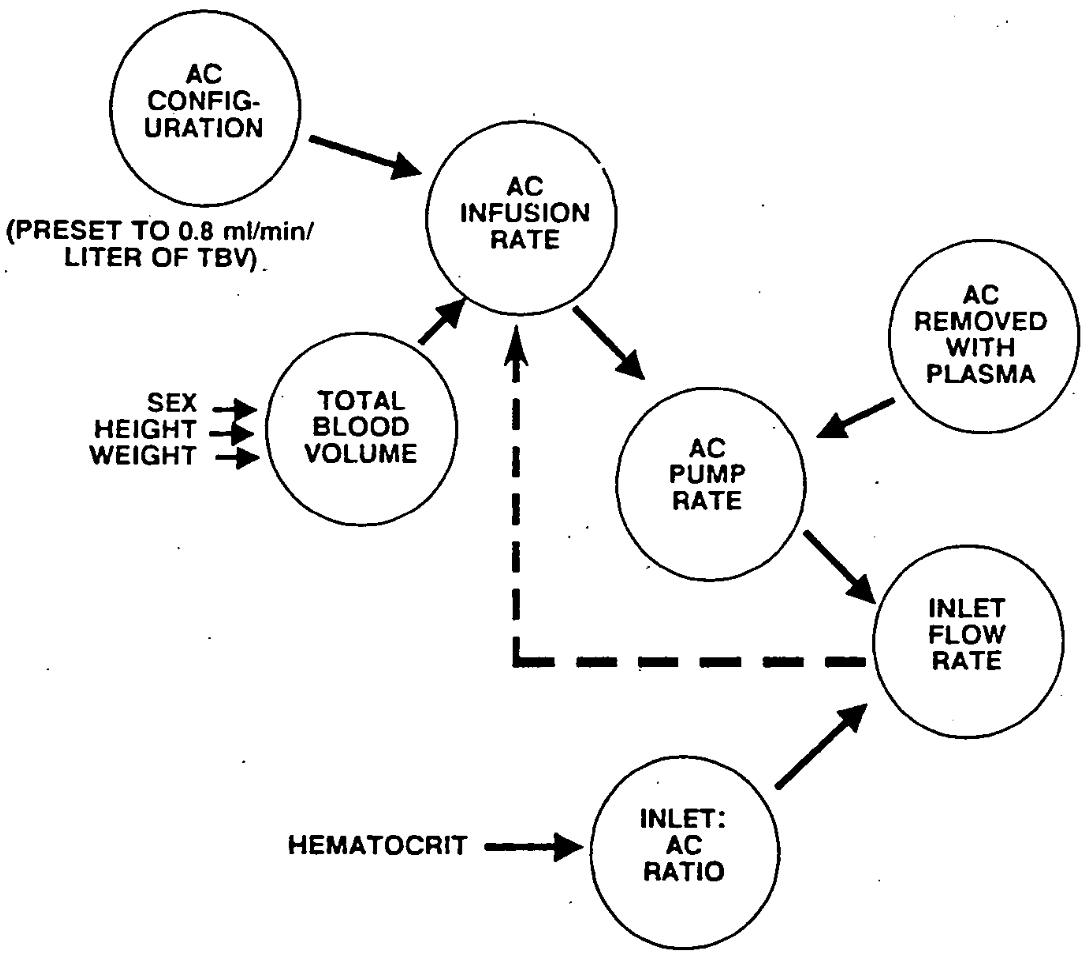
A combination of the AC pump rate and inlet:AC ratio is then used to calculate the inlet flow rate. Therefore, the inlet flow rate will be different for each individual donor or patient. See the following example:

AC Pump Rate × Inlet:AC Ratio = Inlet Flow Rate

Example: *5 ml/min × 9:1 = 45 ml/min*

When plasma is collected concurrently with platelets during ELP and Platelet collect procedures, more blood can be processed, which increases the platelet yield by 5% to 20%. The amount of blood processed is increased because some of the ACD-A added to the donor's inlet flow is removed to the plasma collect bag, and, as discussed above, the Spectra system calculates the amount of ACD-A in the plasma collect bag. Because some of the ACD-A is removed, the donor's inlet flow rate and, consequently, the total amount of blood processed can be increased without an equivalent increase in the rate of ACD-A flow back to the donor. When you select to collect plasma concurrently with platelets, the Spectra system automatically increases the inlet flow rate based on both the donor data you have entered and the amount of ACD-A removed to the plasma collect bag.

The AC infusion rate is based upon the concept that a donor's or patient's ability to metabolize ACD-A is directly related to that individual's total blood volume. Therefore, the COBE Spectra Apheresis System maintains a constant infusion rate of anticoagulant per minute per liter of total blood volume. Refer to Figure 1-19 to see the relationships between donor/patient variables and other variables such as AC pump flow rate, AC infusion rate, AC infusion rate configuration, inlet:AC ratio, and inlet flow rate.



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As indicated in Figure 1-19, the Spectra system first calculates the total blood volume based upon the sex, height, and weight entered as donor or patient data. The AC infusion rate to the donor or patient is then calculated using the total blood volume and the AC infusion rate configuration value that has been programmed into the system. The default value for the AC infusion rate configuration is 0.8 ml/min/liter of TBV. At the direction of the medical director, the AC infusion rate configuration can be changed to a value between 0.8 and 1.1 ml/min/liter of TBV. For additional information on the AC infusion rate configuration, see the **AC Infusion Rate Configuration** subsection of the **SETTING CONFIGURATION VALUES** section later in this INTRODUCTION.

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Total Blood Volume X AC Configuration = AC Infusion Rate

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Any direct changes you make to the inlet flow rate change the AC infusion rate. By increasing the inlet flow rate, you can increase the AC infusion rate to 1.2 ml/min/liter of TBV. If you increase the inlet flow rate to the point that the AC infusion rate exceeds 1.2 ml/min/liter of TBV, the "AC infusion rate exceeds allowable limits" alarm occurs. See SECTION 11 - TROUBLESHOOTING for details on that alarm.

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- Keep the blood from clotting during separation and collection
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In ELP and Platelet collection procedures, the donor's hematocrit is used to calculate the inlet:AC ratio, which is the ratio between inlet flow rate and AC flow rate. The AC ratio varies with the hematocrit because the pH buffering capabilities of the blood in an extracorporeal circuit is directly related to the blood's hematocrit.

(NOTE: For ELP and Platelet collection procedures, the inlet:AC ratio configuration can be changed at the request of the medical director. Refer to the **AC Ratio Configuration** subsection of the **SETTING CONFIGURATION VALUES** section later in this INTRODUCTION. All other Spectra procedures have a default inlet:AC ratio that remains the same for each procedure.)

A combination of the AC pump rate and inlet:AC ratio is then used to calculate the inlet flow rate. Therefore, the inlet flow rate will be different for each individual donor or patient. See the following example:

AC Pump Rate × Inlet:AC Ratio = Inlet Flow Rate

Example: *5 ml/min × 9:1 = 45 ml/min*

When plasma is collected concurrently with platelets during ELP and Platelet collect procedures, more blood can be processed, which increases the platelet yield by 5% to 20%. The amount of blood processed is increased because some of the ACD-A added to the donor's inlet flow is removed to the plasma collect bag, and, as discussed above, the Spectra system calculates the amount of ACD-A in the plasma collect bag. Because some of the ACD-A is removed, the donor's inlet flow rate and, consequently, the total amount of blood processed can be increased without an equivalent increase in the rate of ACD-A flow back to the donor. When you select to collect plasma concurrently with platelets, the Spectra system automatically increases the inlet flow rate based on both the donor data you have entered and the amount of ACD-A removed to the plasma collect bag.

ANTICOAGULATION MANAGEMENT

The use of ACD-A as an anticoagulant in apheresis can cause symptomatic hypocalcemia in certain patients or donors. Mild forms of this condition are generally recognized by peripheral paresthesia, tingling sensations in the extremities, and/or restlessness. Severe forms of this condition can result in significant cardiac dysfunction. Because of these possibilities, COBE recommends that the condition of the donor or patient be assessed frequently throughout the apheresis procedure.

When symptomatic hypocalcemia occurs, the physician should be notified and the inlet flow rate decreased. In this case, the inlet:AC ratio will be maintained and the AC flow rate will decrease. This will effectively lower the infusion rate of anticoagulant to the individual and, thus, should alleviate the symptoms. If decreasing the inlet flow rate does not alleviate hypocalcemic symptoms, the procedure should be stopped and appropriate medical treatment should be prescribed.

CAUTION

Patients or donors with impaired or abnormal citrate and/or calcium metabolism (e.g., liver and renal diseases) may present an increased risk of citrate sensitivity. For this reason, the attending physician should assess appropriateness of such patients or donors for apheresis and prescribe how they should be monitored.

Occasionally, during donor platelet collection, patient platelet depletion, and WBC removal procedures, you may observe clumping in the collect line. This may be alleviated by decreasing the inlet:AC ratio slightly, for example, from 9:1 down to 8.5:1. The Spectra system will respond by decreasing the inlet flow rate, thus providing more citrate per volume of extracorporeal blood while maintaining the rate at which the anticoagulant is returned to the donor/patient. Therefore, there is no increased risk of hypocalcemia because of this change. By providing more citrate to the circuit per volume of blood, the pH and ionized calcium environment will be modified, helping to alleviate clumping. See APPENDIX C – MANUAL AND AUTOMATIC OPERATION for information on changing the inlet:AC ratio. Platelet clumping in the collect line caused by a high concentration of platelets may also be alleviated by increasing the collect pump flow rate from, for example, 1.0 ml/min to 2.0 ml/min.

SETTING CONFIGURATION VALUES

The following nine parameters may be set by pressing the MENU ON/OFF key and choosing Configuration (which is Selection 6.) These nine parameters are independent of one another. Changes to the parameters always affect the current procedure immediately. See the sections of APPENDIX A – KEYBOARD SELECTIONS that discuss the Configuration Selection Messages for information on how to set these configurable parameters.

HEIGHT/WEIGHT UNIT CONFIGURATION

A configuration selection is provided to allow the medical staff using the Spectra system to use either English or metric (centimeters, kilograms) values when entering donor and patient height and weight.

DECIMAL POINT/THOUSANDS SEPARATOR CONFIGURATION

A configuration selection is also provided to allow the medical staff to choose between using the period as the decimal point and comma as the thousands separator or using the comma as the decimal point and period as the thousands separator when entering values via the Spectra keypad.

AC INFUSION RATE CONFIGURATION

The AC infusion rate is the amount of anticoagulant delivered to the donor/patient based on total blood volume. During manufacturing, the AC infusion rate for ELP and Platelet collection procedures is set to a default value of 0.80 ml/minute/liter of TBV. This rate was chosen to reduce the risk of hypocalcemic reactions resulting from a drop in the donor's/patient's plasma ionized calcium . The AC infusion rate can be increased from the default value of 0.80 ml/min/liter of TBV up to a maximum of 1.10 ml/min/liter of TBV.

Increasing the infusion rate will increase the amount of blood processed and, therefore, increase the platelet yield for an equivalent process time. However, this will also increase the hypocalcemic symptoms in the donor. Medical directors need to set this value based upon their own requirements for managing donor reactions and platelet yields.

TOTAL PLASMA IN PLATELET COLLECTION CONFIGURATION

The total volume of plasma removed is the number of milliliters of plasma that the Spectra system is allowed to remove from a donor during a platelet procedure. The system provides configuration selections to control

- The maximum total volume of plasma removed (collected plasma and plasma in cell collect bags combined)
- A percentage of the donor's total blood volume. The default percentage is 12% of total blood volume. You can enter a value between 1% and 15%.

The volume of plasma removed is set initially at a maximum of 600 ml for donors who weigh more than 175 pounds (or 80 kg) and at a maximum of 500 milliliters for donors who weigh less than 175 pounds (or 80 kg). The Spectra system provides configuration selections to change the maximum number of milliliters to values between 10 and 1500 ml and to change the donor weight that will trigger a warning when the maximum number of milliliters of plasma is reached. The allowable donor weight range is 0 to 500 pounds (0 to 230 kg).

When setting new parameters for plasma collect, the Spectra system will automatically prompt you for all three of the following values:

- First bracket: The upper limit of plasma collected for donors who weigh more than the donor weight indicated on this message.
- Second bracket: The amount of plasma permissible if the donor weighs less than the weight set on this message.
- Third bracket: The donor weight that determines which plasma volume to collect.

Pressing the ENTER key saves the values in the brackets. You can only move forward from this set of three messages by pressing ENTER after the third (donor weight cutoff) message. When you press ENTER at this point, you will be returned to the message you were at originally.

For normal donor collections, the maximum volume of plasma removed must be set in compliance with local regulations and applicable standards. It is the responsibility of the physician in charge to prescribe the plasma collection configuration.

NOTE

The Spectra system calculates the amount of anticoagulant removed with the plasma so that maximum volume of plasma collected represents actual plasma volume without anticoagulant.

PATIENT PLASMA VOLUMES TO EXCHANGE CONFIGURATION

The total number of plasma volumes to exchange in a therapeutic plasma exchange procedure needs to be prescribed by the physician in charge.

The Spectra system is programmed during manufacture to allow 1.0 plasma volume to be exchanged. This value can be modified to a value between 0.2 and 5.0 plasma volumes in the Configuration Selection Messages.

AC RATIO CONFIGURATION

The COBE Spectra Apheresis System provides the physician with three range options for automatic setting of the AC ratios (inlet flow rate/AC flow rate) during ELP and Platelet collection procedures. All three levels are based on the donor's hematocrit, as shown in the following table:

AC RATIO AS A FUNCTION OF HEMATOCRIT AT AC RATIO CONFIGURATION SELECTION

Hematocrit	Low AC Ratio	Medium AC Ratio (1.33 X "Low")	High AC Ratio (1.67 X "Low")
35	8.2	10.9	13.7
40	7.3	9.7	12.2
45	6.6	8.8	11.0
50	6.0	7.9	10.0

Higher ratios allow either *more blood to be processed* per unit of time for a constant AC infusions rate or *less AC infusion to the donor* per unit of time for a constant volume of blood processed.

When it is necessary to modify a configuration value, it should be done between procedures. The inlet pump flow rate should be decreased to manage the AC flow rate in response to an anticoagulant reaction during a procedure. The inlet:AC ratio should be reduced directly in response to platelet clumping during a procedure.

For Spectra apheresis procedures, the default inlet:AC ratios set by COBE during manufacturing are as follows:

- ELP and Platelet Collection Procedures: The medium AC ratio in the table above. This ratio can be altered by selecting the low and high AC ratio using the Configuration Selection Messages in APPENDIX A.
- Platelet Depletion Procedures: 6:1
- Therapeutic Plasma Exchange Procedures: 10:1
- Red Blood Cell Exchange Procedures: 13:1
- WBC Removal Procedures:
  - MNC Procedures: 12:1
  - PMN Procedures: 13:1

During any of the above procedures, you may select an inlet:AC ratio other than the configured or default ratio by pressing the INLET:AC RATIO key and entering an inlet:AC ratio between 3:1 and 50:1. Under most circumstances, changes you make to the inlet:AC ratio will change the inlet pump flow rate only; the AC pump flow rate will remain the same. If the change to the inlet:AC ratio is large enough, the AC pump flow rate will change to maintain a constant AC infusion rate. If the inlet flow is maximized (that is, set at 50 ml/min for single-needle platelet procedures) and the inlet:AC ratio is increased, the AC pump flow rate will decrease to maintain the requested inlet:AC ratio. The decision to change the default ratios should be made by the medical staff based on their requirements for the apheresis procedures and products.

HIGH FLOW CONFIGURATION

During high inlet flow (over 45 ml/min) dual-needle ELP and Platelet collection procedures, setting the high flow configuration to "on" guards against red cell spillover into the platelet collection chamber while the red blood cell/plasma interface is being established. It does this by employing an algorithm to allow the interface to stabilize before running over 45 ml/min. The factory-set high flow configuration is "on."

CENTRIFUGE STEP DOWN CONFIGURATION

During ELP and Platelet collection procedures, use of centrifuge step down will decrease the centrifuge speed in stages as the run time increases for procedures with inlet flow rates less than 40 ml/min. At these lower flow rates, centrifuge step down improves platelet yields. Centrifuge step down is disabled automatically at inlet flow rates above 40 ml/min. See the table in centrifuge step down selection message section of APPENDIX A – KEYBOARD SELECTIONS for the specific centrifuge step down speeds.

SINGLE-NEEDLE OPTION CONFIGURATION

Spectra systems that are shipped with the Single-Needle Option come with the single-needle software present but not activated. The Single-Needle Option Configuration allows you to activate the Option when you are ready to begin running single-needle ELP, Platelet, and TPE procedures. It remains activated until you use the Single-Needle Option Configuration to deactivate it.

If you ever stop using single-needle procedures, you would also use the Single-Needle Option Configuration to deactivate the Single-Needle Option.

SECTION 2 - INSTALLATION

INSTALLATION OF SPECTRA™ APHERESIS SYSTEM

This section contains the instructions for installing the COBE Spectra™ Apheresis System. The environmental requirements and storage procedures are also provided. The procedures described in this section are to be performed by a technician who has been thoroughly trained in performing maintenance on the Spectra system.

ENVIRONMENTAL REQUIREMENTS

The Spectra system requires 115 volts ac, 50/60 Hz, 8 ampere service (100, 220, or 240 volts, 50/60 Hz in some areas outside the USA). The maximum power consumption is 1000 watts. It is essential that the three-wire receptacle be properly grounded and in good condition. If there are any questions concerning the condition of the wiring or whether it is grounded, have the wiring checked by a qualified electrician.

WARNING

Do not use alternate power plugs or adapters that disconnect the green wire safety ground.

WARNING

Do not use the Spectra Apheresis System in an explosive atmosphere.

PACKING LIST

Check that all the following items are included with the Spectra system:

- Two *COBE Spectra Operator's Manuals*
- Collect Flow Path Overlay, TPE Flow Path Overlay, and RBCX Flow Path Overlay (1 each)
- Disposable Blood Tubing Set (for setup and checkout)
- Single-Stage Channel Filler and Dual-Stage Platelet Channel Filler (1 each)
- Power Cord
- Maintenance Kit

1. Check for scratches, dents, and broken parts.
2. Attach the IV pole to the top rear of the system, using the screws provided in the mounting holes.
3. Attach the AC (anticoagulant) level detector to the IV pole on the left side of the system.
4. Locate the two screw fasteners near the top of the front panel rear door. (See Figure 2-1.) Turn the fasteners counterclockwise and open the door.

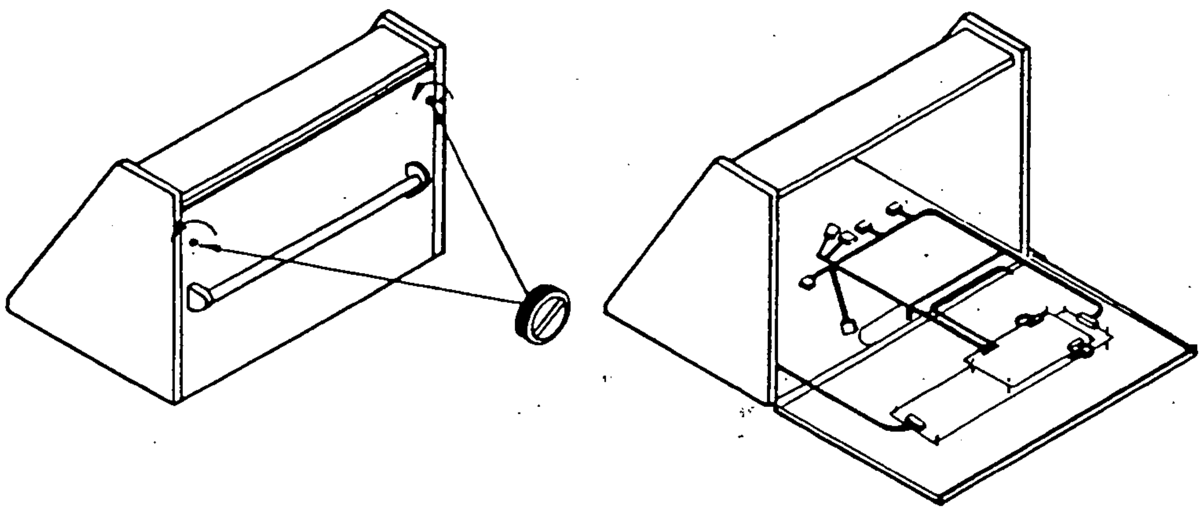

Figure 2-1. Rear Front Panel

5. Make sure that the printed circuit cards attached to the rear door are held securely in place with the white plastic clips around the edge of the board. Also, check that there is no visible damage to the interior of the front panel. (See Figure 2-1.)
6. Make sure that all valve, pump, sensor, transducer, and harness connectors are properly attached.
7. Close and secure the front panel rear door.
8. Locate the two screw fasteners on the left-hand side of the centrifuge chamber rear door. (See Figure 2-2.) Turn the fasteners counterclockwise and open the door.

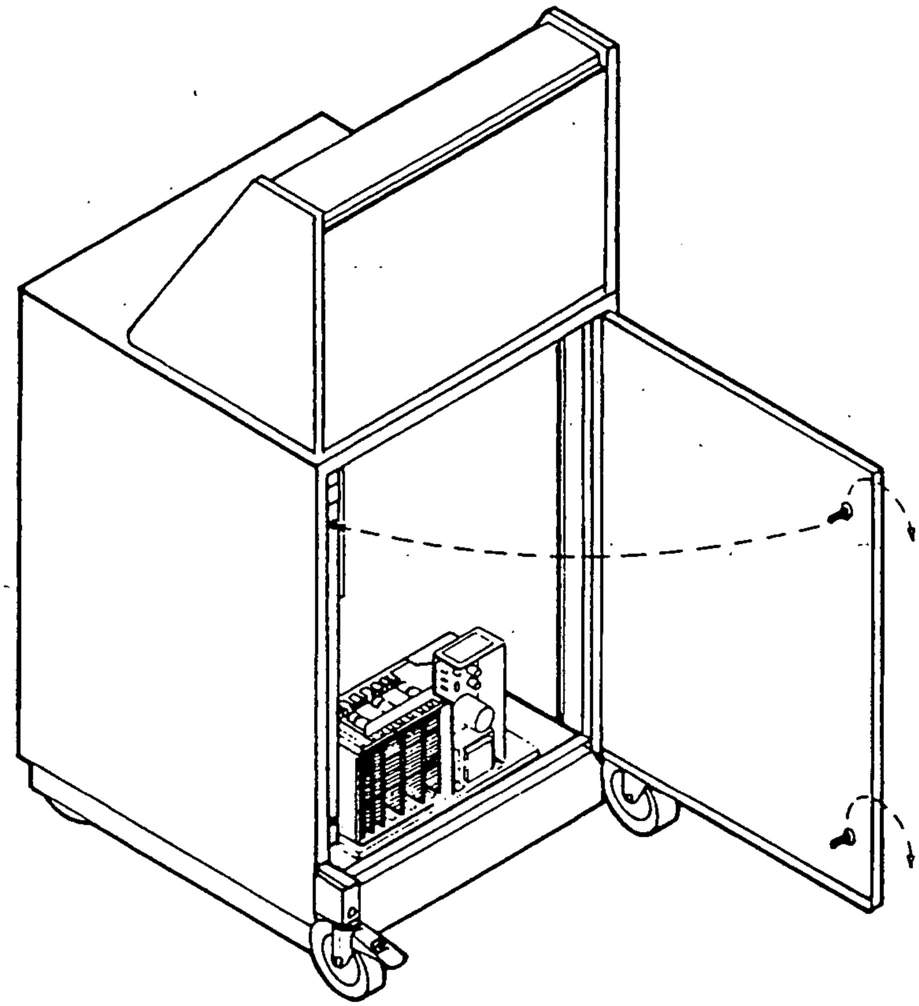

Figure 2-2. Rear Centrifuge Chamber

9. Check that the printed circuit cards located in the card cage are securely in place. The cards should be parallel and even with the end of the cage. Also, check that there is no visible damage to the interior of the system. (See Figure 2-2.)

10. Close and secure the centrifuge chamber rear door.

11. Call COBE Customer Engineering Representative if you find anything wrong or have any questions during assembly of the Spectra Apheresis System.

MOVING

Whenever the Spectra Apheresis System is transported over any rough surfaces or in a vehicle, remove the filler from the centrifuge.

STORAGE

The Spectra Apheresis System must be prepared for long-term storage as follows:

1. Wipe the outside of the system with a soft, dry cloth to remove all dust.

2. Clean and dry the interior of the centrifuge chamber around the centrifuge.

3. Cover the entire system with a plastic sheet and secure with tape.

NOTE

The Spectra system must be stored in an insect/vermin free environment with temperature between −18°C and +54°C (0°F and 130°F). Ambient storage humidity must be 0% to 80%, noncondensing.

INSTALLATION OF RETURN FLOW CONTROLLER

This section contains the instructions for installing the COBE Spectra™ Single-Needle Return Flow Controller.

PACKING LIST

Check that all the following items are included with the Spectra Single-Needle Return Flow Controller:

- One Return Flow Controller (Catalog Number 951000-000)

- Two Disposable Spectra Single-Needle Sets (Catalog Number 777000-100) for modifying Platelet and TPE Sets for use with single-needle procedures. Each set includes
  - One Single-Needle Bag
  - One "Y" Connector

INSTALLATION

The Return Flow Controller may be clamped to either the top horizontal segment or side vertical segments of the Spectra IV pole.

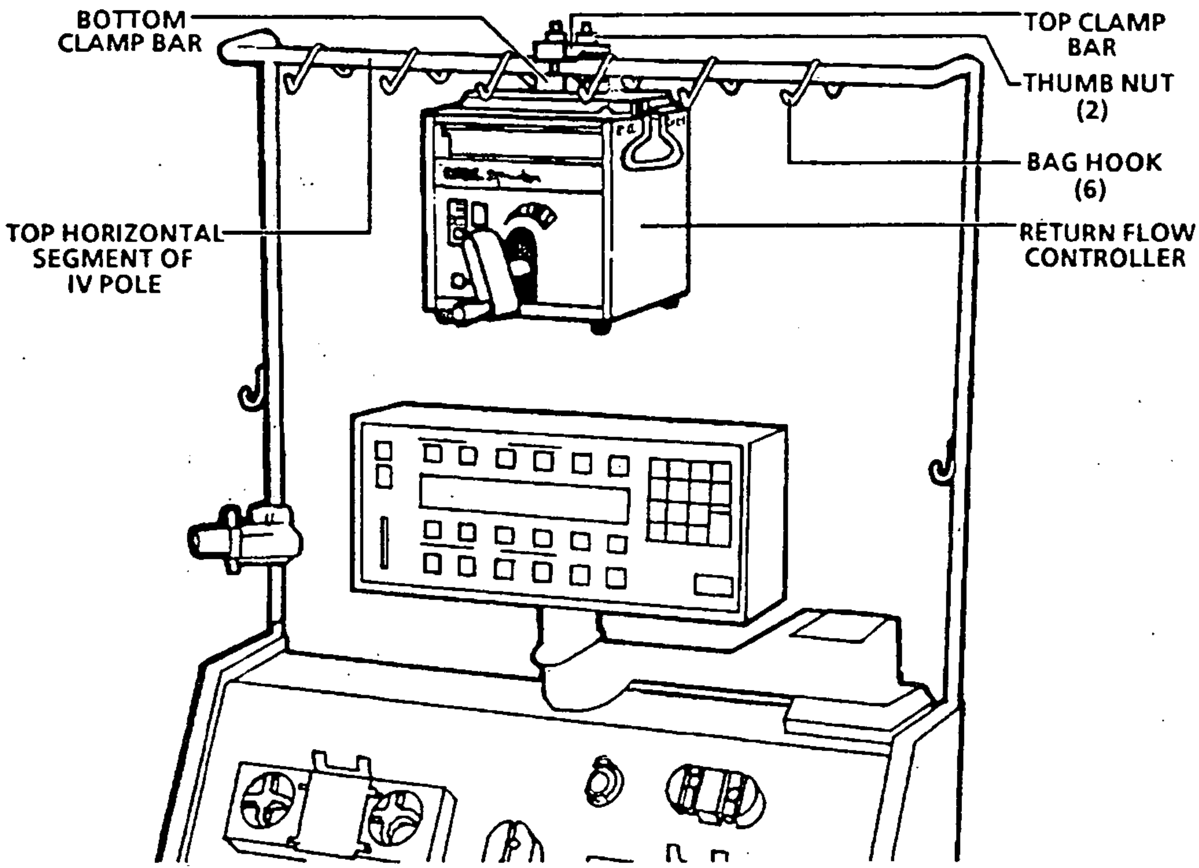

Figure 2-3. Installation of Return Flow Controller on Horizontal Segment of IV Pole

To clamp the Return Flow Controller to the horizontal segment of the IV pole:

1. Unscrew the two thumb nuts (Figure 2-3) until the slotted top clamp bar will pivot one-quarter turn.
2. Place the bottom clamp bar's V-seat (Figure 2-3) against the IV pole.
3. Continue to unscrew the thumb nuts until you can pivot the slotted top clamp bar back against the threaded post.
4. Use enough force to tighten the thumb nuts down onto the top clamp bar on the IV pole such that the Return Flow Controller is secure.

In this position, the cross bars (bag hooks) on the horizontal segment of the IV pole will prevent the Return Flow Controller from rotating around the IV pole.

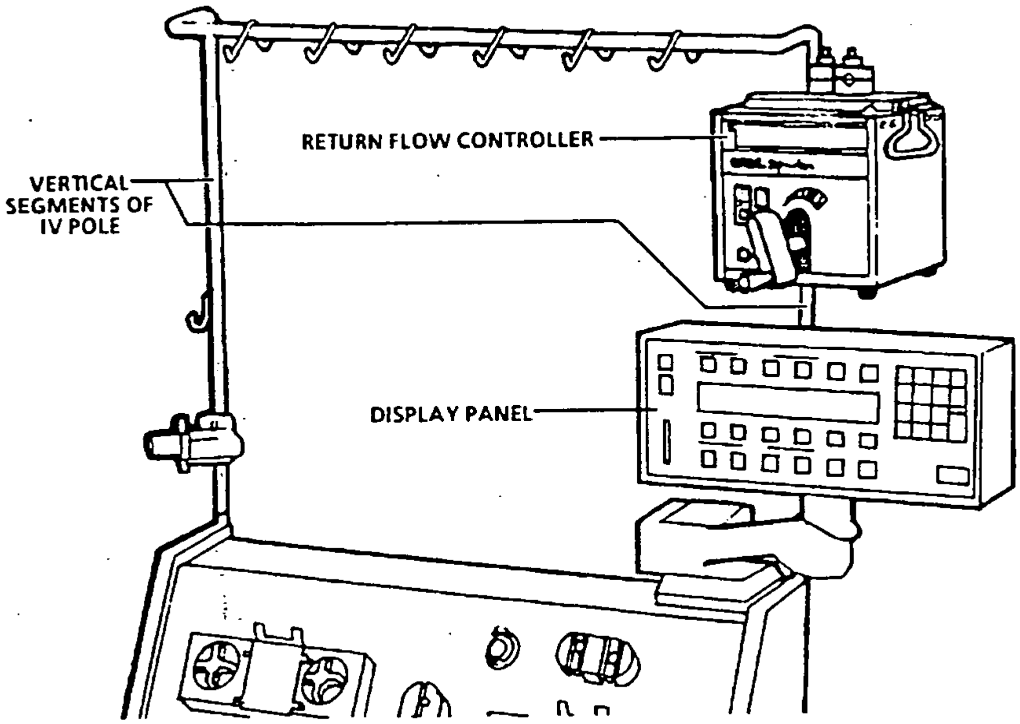

Figure 2-4. Installation of Return Flow Controller on Right Segment of IV Pole

To clamp the Return Flow Controller to the right segment of the IV pole (Figure 2-4), use both of the Return Flow Controller's two back-mounted clamps as follows:

1. Unscrew the two thumb nuts (Figure 2-5) until the slotted top clamp bar on the back of the Return Flow Controller will pivot one-quarter turn.
2. Place the bottom clamp bar's V-seat (Figure 2-5) against the IV pole.
3. Continue to unscrew the thumb nuts until you can pivot the slotted top clamp bar back against the threaded post.
4. Use enough force to tighten the thumb nuts down onto the top clamp bar on the IV pole such that the Return Flow Controller is secure.

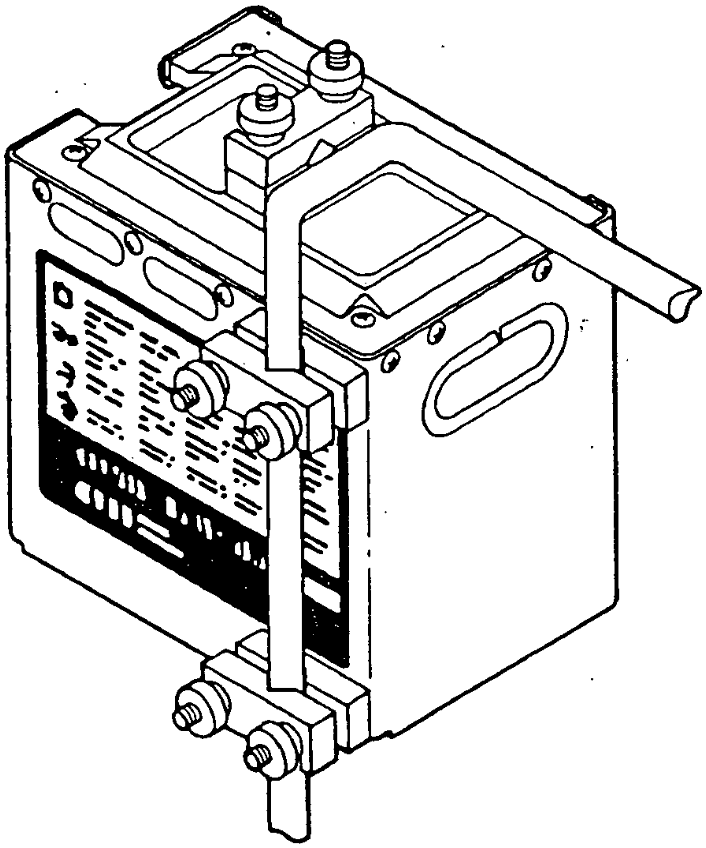

Figure 2-5. Back View of Return Flow Controller Showing IV Pole Clamps

CAUTION

Be sure that the Return Flow Controller is mounted high enough to clear the Spectra system's control panel. See Figure 2-4. This will prevent inadvertent damage to either assembly when the control panel is swiveled.

When the Return Flow Controller is mounted on the right vertical segment of the IV pole, carefully check door clearances when moving the Spectra system, as the Return Flow Controller must be rotated inward to clear some doorways.

OTHER RETURN FLOW CONTROLLER POSITIONS

When mounting the Return Flow Controller in other positions or setting it on its rubber feet on a nearby surface, ensure that there are not more than 3 feet between the Spectra return air chamber (to which the single-needle bag is attached) and the right side of the Return Flow Controller. This allows enough length for the tubing running between the single-needle bag and the return air chamber.

RETURN OF USED PRODUCT

If this product must be returned to COBE Laboratories, Inc., for any reason, a returned goods authorization (an RGA number) is required from COBE prior to shipping.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number, may be obtained from the COBE Returned Goods Coordinator, Quality Assurance Department (1-800-525-COBE).

CAUTION

It is the responsibility of the health care institution to adequately prepare and identify the product for return shipment.

The shipping address for returned goods is:

COBE Laboratories, Inc.
Returned BCT Products
1175 Oak Street
Lakewood, CO 80215-4407

3a-ELP Operation

SECTION 3A - ELP™ DUAL-NEEDLE OPERATION

This procedure is intended for use when a dual-needle Extended Life Platelet blood tubing set is used to collect donor platelets for storage up to 5 days. See SECTION 3B – ELP™ SINGLE-NEEDLE OPERATION for the ELP single-needle procedure.

REQUIRED EQUIPMENT AND SUPPLIES

DUAL- AND SINGLE-NEEDLE PROCEDURES

- COBE Spectra™ Apheresis System
- Dual-stage platelet channel filler
- Collect flow path overlay
- Anticoagulant (ACD-A – each 100 ml contains: 2.2 g sodium citrate hydrous, 730 mg citric acid anhydrous, and 2.45 g dextrose hydrous)
- 0.9% sodium chloride for injection (1000 ml). When only single-port saline containers are available and/or hypersensitivity reactions associated with ethylene oxide sterilization must be avoided, see **HOW TO USE AN ALTERNATIVE SINGLE-PASS PRIME PROCEDURE** in SECTION 10 – HELPFUL HINTS.
- Forceps or hemostats

DUAL-NEEDLE PROCEDURES ONLY

- Disposable dual-needle ELP™ blood tubing set (Catalog Number 777003-000)

NOTE

During Dual-Needle ELP collections, the COBE Spectra Apheresis System collects leukocyte-poor platelet concentrate with an average WBC content of 4.9 X 10^5 per product.[1] The actual WBC counts may increase depending upon

- Limitations of WBC counting technique
- Spillovers during the procedure
- Concurrent plasma collection

[1] Dzik, W.H., Tagosta, A., and Cusack, W.F., Flow Cytometric Method for Counting Very Low Numbers of Leukocytes in Platelet Products. *Vox Sang* 1990; 59: 153-59.

SETTING UP EQUIPMENT

Operator Action	System Action

Check System

1. Plug in Spectra Apheresis System.

2. Turn power switch ON.

The system will go through a short self-check to ensure that the various power supplies are operating at the correct voltage.

Power up tests in progress.

COBE Spectra (Program Revision _). Press CONTINUE to load tubing set.

All Pumps -- Stopped
Centrifuge -- Stopped
Waste Valve -- *Load Position
Plasma Valve -- *Load Position
Collect Valve -- *Load Position
RBC Line Valve -- Open
Return Line Valve -- Open
*Refer to Appendix A for an explanation of valve positions.

3. Verify the following:

   - Yellow warning LED is illuminated.
   - "COBE Spectra (Revision _)" is displayed.
   - PAUSE LED is flashing.
   - Cartridge clamps are in load position.

Install Filler

1. Press UNLOCK COVER key.

2. Slide centrifuge cover back.

3. Lower centrifuge door.

4. Rotate centrifuge so centrifuge loading port (with alignment dot) is facing the front. (See Figure 3A-1.)

5. If a single-stage channel filler is in place, remove it as follows:

Operator Action	System Action
7. Place filler over centrifuge assembly, and press down until filler locking pin is securely in place.	
8. Lower filler latch.	
9. Lift up on filler to ensure it is securely in place.	
10. Close centrifuge door and cover.	
11. Install collect flow path overlay on front panel.	

Operator Action	System Action
6. Remove return line coil and remove white paper tapes. (See Figure 3A-2.)	
a. Hang donor/patient connection on hook on left side of IV pole. (For identification purposes, the two lines attached to this connection are taped together with blue tape until they reach the front panel.)	
b. Place return saline line over the top of the system.	
7. Hang bags on one hook on the IV pole.	
8. Remove return pump cartridge and snap it into the cartridge clamp between plasma and collect/replace pump. (COBE label on cartridge should be facing up.)	
9. Remove access pump cartridge and snap it into the cartridge clamp between the AC and inlet pumps. (COBE label on cartridge should be facing up.)	
10. Place AC line over top of the system.	
11. Ensure all tubing is clear of pumps and untangled.	
12. Press CONTINUE key to load tubing into pump housings.	Cartridge clamps are retracted and tubing headers are threaded onto pump rotors

Loading pumps.
Load

All Pumps	-- 48 ml/min
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Collect Position
Collect Valve	-- Collect Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Time	-- 10 seconds

Operator Action	System Action
13. Verify all four pumps are loaded.	After pumps are loaded, valves automatically open to load position.
14. Put lines in collect/replace and plasma valves.	
15. Place sensor in return pressure sensor housing. Press down and turn clockwise to lock in place.	

Operator Action	System Action

3. Press UNLOCK COVER key.

4. Slide centrifuge cover back.

5. Lower centrifuge door.

6. Rotate centrifuge so loading port (No. 8 in Figure 1-13) is open to the front.

7. Ensure that centrifuge collar holder is resting on the outer rim of the filler. (See position of centrifuge collar holder in Figure 3A-1.) If centrifuge collar holder is not resting on the outer rim of the filler, push filler latching pin (No. 5 in Figure 1-13) toward center of centrifuge, raise filler latch (No. 6 in Figure 1-13), and place it on the outer rim.

8. Extend centrifuge loop to full length to ensure four-lumen tubing is not twisted.

9. Fold channel in half as follows (see Figure 3A-3):
   - Hold channel so control chamber is toward you.
   - Place hands on either side of control chamber and press sides of channel together.
   - Channel should be collapsed with control chamber at one end, forming a banana shape.

CAUTION

Be careful not to stretch the tubes when folding the dual-stage channel.

10. Thread channel through lower loading port (No. 8 in Figure 1-13) and pull it out from the top.

11. Position channel in correct orientation above filler slots before placing centrifuge collar (Figure 3A-3) into centrifuge collar holder (Figure 3A-1).

12. Load centrifuge collar into centrifuge collar holder, closing cover over collar.

13. Lower filler latch into locked position.

14. Press channel into position, ensuring it is completely loaded in filler. Start at control chamber and work around in both directions toward the collection chamber (Figure 3A-3).

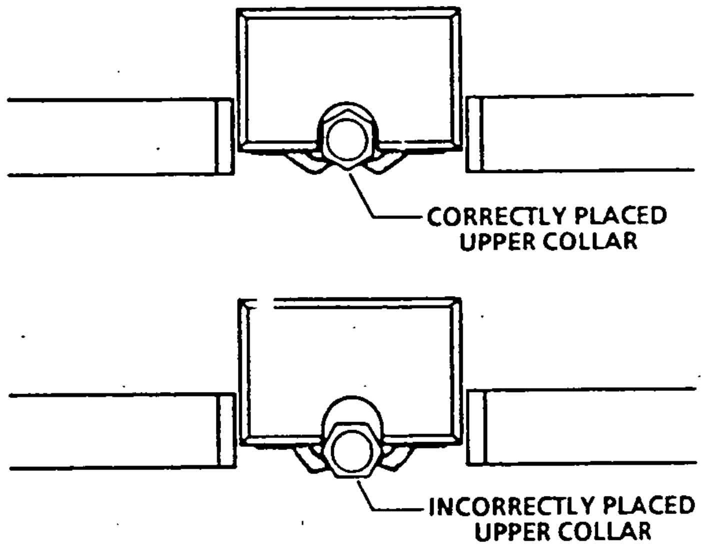

Figure 3A-4. Upper Collar Placement

Operator Action	System Action
19. Use a "flossing" action to place four-lumen tubing in exit slot on right side of system. Ensure that the line to the Collect Concentration Monitor is not kinked or twisted.	
20. Rotate centrifuge several times to ensure tubing does not twist and upper bearing remains in place.	

WARNING

Inspect all lines, especially those in the centrifuge and on the front panel, to ensure they are not kinked. Lines that are occluded, or partially occluded, may lead to the procedure not operating correctly.

21. Close centrifuge door and cover.

Operator Action	System Action
2. Press 2 key to select Dual needle if Single-Needle Option is installed.	
	Clamp access and return lines. Close both saline lines. Press CONTINUE. All Pumps -- Stopped Centrifuge -- Stopped Waste Valve -- Load Position Plasma Valve -- Load Position Collect Valve -- Load Position RBC Line Valve -- Open Return Line Valve -- Open
3. Close white pinch clamps on access and return lines near needle connections. Close roller clamps on access and return saline lines.	
4. Press CONTINUE key.	Connect Platelet tubing set to fluid containers. Press CONTINUE. All Pumps -- Stopped Centrifuge -- Stopped Waste Valve -- Load Position Plasma Valve -- Return Position Collect Valve -- Return Position RBC Line Valve -- Open Return Line Valve -- Closed

CAUTION

Use aseptic technique throughout this procedure.

5. Connect AC line to anticoagulant container. Place AC line in AC level detector, ensuring filter is placed below detector.

6. Connect inlet and return saline lines to same saline container. Using aseptic technique, clean injection port before inserting metal spike into it. Then place plastic spike in spike port (after removing cover). Fill drip chambers 1/2 full.

Operator Action	System Action
	Priming anticoagulant line. (Platelet Set) Prime

AC Pump	-- 100 ml/min
Inlet Pump	-- 150 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Inlet Divert Position
Plasma Valve	-- Collect Position
Collect Valve	-- Collect Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- 30 ml AC
Approximate Time	-- 18 seconds

10. Move bags to correct positions on IV pole as follows:

●	●	●	●	●	●
AC	Saline	Waste	Plasma	ELP Collect	ELP Collect

11. Close slide clamp between ELP collect bags. (Platelet concentrate should be collected into one bag for optimal 5-day storage. If collect volume is over 300 ml at end of procedure, transfer about one-half of platelet concentrate to the second ELP collect bag.)

12. Donor data can be entered before tubing set is primed, during Prime mode, or after priming is complete:

    a. To enter donor data before Prime mode, select set type (1 = Platelets or ELP) and press MENU ON/OFF key. Continue with Step 12d.

    b. To enter donor data during Prime mode, press MENU ON/OFF key. Continue with Step 12d.

    c. To enter donor data after priming is complete, continue with Step 13.

    d. Press 1 key to select "Data Entry". (Refer to following section, **Enter Donor Data**, for instructions on how to enter donor information.)

Operator Action | **System Action**

Priming centrifuge channel. Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/min
Plasma Pump	-- 20 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 20 ml Inlet
Approximate Time	-- 10 seconds

Priming centrifuge channel. Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/min
Plasma Pump	-- 20 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 20 ml Inlet
Approximate Time	-- 10 seconds

Priming centrifuge channel. Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/min
Plasma Pump	-- 10 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 1600 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 20 ml Inlet
Approximate Time	-- 10 seconds

Operator Action	System Action
	Testing sensors, valves, and pumps. Prime

All Pumps	-- Vary Flow Rate
Centrifuge	-- Varies
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Varies Position
RBC Line Valve	-- Varies Position
Return Line Valve	-- Varies Position
Approximate Time	-- 60 seconds

The various valves and pumps change position as the system removes air from channel and does a series of self-checks.

Prime access and return connections.
Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

13. Open white pinch clamps near access needle. Allow saline to fill needle by gravity. Close white pinch clamps.

14. Open white pinch clamp near return needle connection. Allow saline to fill luer lock connection by gravity. Close white pinch clamp.

15. Press CONTINUE key.

Close access saline line. Clamp access line. Press CONTINUE to test AC ratio.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Operator Action | **System Action**

NOTE

To clear saline from return saline drip chamber (so saline drip can be observed), do the following:

1. Clamp line below chamber.
2. Invert container and squeeze saline from drip chamber into saline container.
3. Rehang saline container.
4. Remove clamp.

19. Continue with **Enter Donor Data** steps.

Enter Donor Data

The Spectra system will customize platelet collections by using donor data to calculate pump flow rates, centrifuge speed, collect volume, inlet/anticoagulant ratio, and procedure time.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

```
Select sex:   1 = Male,  2 = Female.
   (ENTER = Male)
```

1. Enter donor sex:

- Press 1 if male.
- Press 2 if female.
- Press ENTER for default (data in parentheses).

(English units - enter feet):

```
Enter height,
in feet:        {0} and/or inches:   0
```

(Range: 1 to 7 feet)

Operator Action	System Action
	NOTE If default values for hematocrit are used, ini·.t:AC ratio will be based on default value rather than on donor hematocrit and, hence, may not yield best collection performance.
	Enter platelet pre-count, in cells/microliter: {250} x 1000 (Range: 1 to 2,000 = 1,000 to 2,000,000/ul)
6. Enter donor platelet pre-count in thousands per microliter. Then press ENTER.	The Spectra system will use a default value of 250,000/ul. **NOTE** If default value for platelet pre-count is used, yield and concentration calculations will be based on default value and may not give accurate values for predicted yield and concentration.
	1 = no plasma, 2 = collect plasma. (ENTER = no plasma)
7. The Spectra system allows plasma to be concurrently collected with platelets: a. Press 1 or ENTER key if you do not want to concurrently collect plasma. b. Press 2 if you want to concurrently collect plasma.	
	Yield = _._E11, collect = _____, conc = _,___, plasma = ____, time = ___ min. OK (YES/NO)?
	The Spectra system uses donor data (entered by the operator) and microprocessor algorithms to calculate and show the following information on the platelet yield display: • Platelet yield displayed to the eleventh power (for example, 4E11 = 4 x 10^{11}). • Collect volume displayed in milliliters. • Platelet concentration in collect bag displayed in thousands per microliter (x 1000). (Default value is 1,400,000 per microliter.)

Table 3A-1. Effect Changing One Platelet Collection Value Has on Others When Plasma Is Not Being Collected or a Fixed Plasma Volume Has Been Entered

Changed Value	Affected Value
Run Time	Platelet Yield Inlet Volume Platelet Collect Volume AC Volume
Inlet Flow	AC Infusion Rate Platelet Yield Inlet Volume Platelet Collect Volume AC Volume
Platelet Collect Volume	Increased Volume = Lower Platelet Concentration and Slight Increase in Platelet Yield Inlet Volume AC Volume Inlet Flow Decreased Volume = Higher Platelet Concentration and Slight Decrease in Platelet Yield Inlet Volume AC Volume Inlet Flow
Platelet Collect Concentration	Increased Platelet Concentration = Lower Platelet Collect Volume and Slight Decrease in Platelet Yield Inlet Volume AC Volume Inlet Flow Decreased Platelet Concentration = Higher Platelet Collect Volume and Slight Increase in Platelet Yield Inlet Volume AC Volume Inlet Flow

Operator Action	System Action
	Yield = _._ E11, collect = _____, conc = _,___, plasma = ___, time = ___ min. Inlet = ___._

10. Using arrow keys, change selected value. The up arrow key increases the value, and the down arrow key decreases it. Affected value(s) will also be changed. When satisfied that changed and affected values are appropriate, press ENTER to return to *platelet yield message* (follows Step 7 above). Press CLEAR key to return to *platelet settings message* (follows Step 8 above).

    When changing platelet and plasma collection values, the following value ranges are allowed for changed values.

Changed Value	Allowed Range
Run Time	10-999 min
Inlet Flow	15-150 ml/min
Platelet Collect Volume	10-9999 ml
Platelet Collect Concentration	100-8,000 (100,000-8,000,000/ul)
Plasma Volume	0-999 ml*

* Maximum allowable plasma volume can be increased to 1500 ml via the Total Plasma Collect Volume Entry Configuration. (See Configuration Selection Messages in Appendix A.)

11. Follow the steps below to monitor the effect that increasing the inlet flow rate has on the AC infusion rate and to verify that the AC infusion rate does not exceed the prescribed limit for the donor:

    a. Press MENU ON/OFF key.

	1 = Data Entry, 2 = Pressure Display, 3 = CCM, 4 = Air Remove, 5 = Strobe, 6 = Config., 7 = SN.

    b. Press 1 key to select "Data Entry."

Operator Action	System Action
4. Close roller clamp on access saline line.	

Start Run Mode

1. Press CONTINUE key to start system in Run mode.

All pumps will start and centrifuge speed will increase based on parameters preset by donor data and Spectra algorithms.

AC	Inlet	Plasma	Collect / Replace	Inlet : AC Ratio	Spin RPM
__.__	___.__	___.__	___.__	___.__	_____

Diverting prime saline.

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- _ : 1
Centrifuge	-- _______ rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

NOTE

It is normal that a small amount of red cells may be diverted to the waste bag when prime saline is diverted.

2a. If you want to divert the prime saline to the waste bag, continue with Step 3.

OR

2b. If you do not want to divert the prime saline to the waste bag and, instead, want to return it to the donor, follow these steps:

- Press the CHANGE MODE key.
- Press 3 key to select Run.
- Close the roller clamp on the return saline line. (The system will not prompt you to do this.)
- Press CONTINUE key.
- Continue with Step 4, but **do not** press CLEAR.

Operator Action	System Action

AC	Inlet	Plasma	Collect Replace	Inlet : AC Ratio	Spin RPM
__.__	____.__	____.__	____.__	____.__	PLTC
____	______	______	______	______	
AC	Inlet	Plasma	Collect Replace	Time Min	Procedure

NOTE

If centrifuge step down is enabled, refer to *centrifuge step down selection message* in APPENDIX A.

AC Pump	-- ___.__	ml/min
Inlet Pump	-- ___.__	ml/min
Plasma Pump	-- ___.__	ml/min
Collect Pump	-- ___.__	ml/min
Ratio	-- _ : 1	
Centrifuge	-- ______	rpm
Waste Valve	-- Closed	
Plasma Valve	-- Variable Position	
Collect Valve	-- Variable Position	
RBC Line Valve	-- Open	
Return Line Valve	-- Open	

AC	Inlet	Plasma	Collect Replace	Inlet : AC Ratio	Spin RPM
__.__	____.__	____.__	____.__	____.__	______

Establishing interface, Inlet = 45 ml/min.

This screen is displayed during dual-needle ELP procedures if all three situations below are true:

- The high flow protocol is enabled. (See *high flow selection message* in APPENDIX A.)
- The inlet flow rate is greater than 45 ml/min.
- The calculated or displayed inlet volume is less than 500 ml. During this step, the system is establishing a stable red blood cell/plasma interface. The inlet flow rate will increase after 500 ml of inlet volume have been processed.

If the above screen is displayed, the actual flow rates will be lower than those displayed in the screen.

AC	Inlet	Plasma	Collect Replace	Inlet : AC Ratio	Spin RPM
__.__	____.__	____.__	____.__	____.__	PLTC
____	______	______	______	______	
AC	Inlet	Plasma	Collect Replace	Time Min	Procedure

Operator Action	System Action
6. Press 2 key to continue Run mode. (To start Rinseback mode, press 1 key and skip to **Start Rinseback Mode** section.)	If no selection is made, a shutdown alarm will occur after 10 minutes and the pumps will stop.

Increase flashing target limits.
Target

AC	Inlet	Plasma	Collect Replace	Time Min	Procedure

AC Pump -- ___.__ ml/min
Inlet Pump -- ___.__ ml/min
Plasma Pump -- ___.__ ml/min
Collect Pump -- ___.__ ml/min
Ratio -- __ : 1
Centrifuge -- ______ rpm
Waste Valve -- Closed
Plasma Valve -- Variable Position
Collect Valve -- Variable Position
RBC Line Valve -- Open
Return Line Valve -- Open

Operator Action	System Action
7. Select flashing target value on bottom row of display.	Inlet volume processed and time elapsed are only values that flash.
8. To increase inlet volume or time, press appropriate key.	
9. Enter new target value on numeric keypad. Then press ENTER.	Run mode continues until target values are reached. There are audio and visual warnings when Run mode is complete.

End of Run: 1 = Rinseback, 2 = Continue Run.
PLTC

AC	Inlet	Plasma	Collect Replace	Time Min	Procedure

AC Pump -- ___.__ ml/min
Inlet Pump -- ___.__ ml/min
Plasma Pump -- ___.__ ml/min
Collect Pump -- ___.__ ml/min
Ratio -- __ : 1
Centrifuge -- ______ rpm
Waste Valve -- Closed
Plasma Valve -- Variable Position
Collect Valve -- Variable Position
RBC Line Valve -- Open
Return Line Valve -- Open

Operator Action | **System Action**

Rinseback: Collecting step is skipped if collect valve is in return position. For example, during a red cell spillover, CCM moves collect valve automatically to return position.

> Clamp and disconnect collection bags.
> Press CLEAR.

AC Pump	-- Stopped
Inlet Pump	-- 50.0.ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

NOTE

If the inlet flow was higher than 50 ml/min during the Run mode, the inlet pump will run at the higher rate.

5. **IMPORTANT**: Clamp or seal collect line above and below luer connection and remove platelet product bags. If more than 300 ml of platelet concentrate has been collected, first store about one-half in each platelet product bag. If platelet concentrate volume is less than 300 ml, store in one bag. For the steps to follow to collect a double-platelet product, see **HOW TO PREPARE A DOUBLE-PLATELET PRODUCT** in SECTION 10 – HELPFUL HINTS.

   If concurrent plasma has been collected, clamp or seal plasma line and remove plasma product bag.

Operator Action	System Action

NOTE

No flow to or from donor during this step.

Rinseback: Evacuating channel. Rinse.

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma Pump	-- 50.0 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 100 ml Plasma
Approximate Time	-- 150 seconds

The Spectra system opens return line valve so free red cells can be returned to donor. Channel is collapsed to reduce extracorporeal blood volume.

Rinseback: Rinsing channel. Rinse.

AC Pump	-- Stopped
Inlet Pump	-- 50.0 ml/min
Plasma Pump	-- 50.0 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 58 ml Inlet
Approximate Time	-- 70 seconds

The Spectra system allows additional saline to enter channel to flush final red cells back to donor.

NOTE

If the inlet flow was higher than 50 ml/min during the Run mode, the inlet pump will run at the higher rate.

REMOVING ELP DISPOSABLES

Operator Action | **System Action**

(See Figure 1-13.)

1. Place ends of donor access and return lines in appropriate biohazard disposal container.
2. Press UNLOCK COVER key.
3. Slide centrifuge cover back.
4. Lower centrifuge door.
5. Remove four-lumen tubing from exit slot on right side of the system.
6. Remove collar from upper collar holder.
7. Remove upper bearing from upper bearing holder.
8. Remove lower bearing from lower bearing holder.
9. Push filler latching pin toward center of centrifuge and raise filler latch.
10. Pull tubes from slots in filler.
11. Pull channel from filler.
12. Open hinged cover on centrifuge collar holder and remove collar.
13. Raise channel above filler.
14. Fold channel in half and pull through loading port.
15. Discard channel in appropriate biohazard disposal container. (Channel will still be connected to tubing.)
16. Close centrifuge door and cover.

3b-ELP SN
Operation

SECTION 3B - ELP™ SINGLE-NEEDLE OPERATION

This procedure is intended for use when a single-needle Extended Life Platelet blood tubing set is used to collect donor platelets for storage up to 5 days. See SECTION 3A – ELP™ DUAL-NEEDLE OPERATION for ELP dual-needle procedure.

REQUIRED EQUIPMENT AND SUPPLIES

DUAL- AND SINGLE-NEEDLE PROCEDURES

- COBE Spectra™ Apheresis System
- Dual-stage platelet channel filler
- Collect flow path overlay
- Anticoagulant (ACD-A – each 100 ml contains: 2.2 g sodium citrate hydrous, 730 mg citric acid anhydrous, and 2.45 g dextrose hydrous)
- 0.9% sodium chloride for injection (1000 ml). Note that since the procedure for using the single-needle ELP blood tubing set already makes use of a single-pass prime, the **HOW TO USE ALTERNATIVE SINGLE-PASS PRIME PROCEDURE** in SECTION 10 – HELPFUL HINTS only applies to dual-needle ELP procedures.
- Forceps or hemostats

SINGLE-NEEDLE PROCEDURES ONLY

- Disposable single-needle ELP™ blood tubing set (Catalog Number 777003-100)
- Return Flow Controller (Catalog Number 951000-000)
- Blood pressure cuff

NOTE

Using the same donor, a 10%-15% longer procedure time may be required to produce a yield of single-needle platelet product equivalent to the yield of a dual-needle platelet procedure.

NOTE

During Single-Needle ELP collections, the COBE Spectra Apheresis System collects leukocyte-poor platelet concentrate with an average WBC content of 3.5 X 10^7 per product. The actual WBC counts may increase depending upon

- Limitations of WBC counting technique
- Spillovers during the procedure
- Concurrent plasma collection

WARNING

If any of the following occur, the disposable ELP blood tubing set is no longer functionally closed and product should not be stored beyond 24 hours:

1. **Failure in first attempt to successfully insert access needle.**
2. **Disconnection of access needle from tubing set.**
3. **Use of injection site on access manifold for blood samples or infusion of medication or parenteral solutions.**
4. **Disconnection of either plasma or platelet collect bag before it is sealed.**
5. **Use of sample site on platelet collect bag for blood samples or infusion of medication or parenteral solutions.**
6. **Compromise in integrity of tubing set for any reason.**
7. **Use of luer connection below platelet collect bags for collection of blood samples or infusion of medication or parenteral solutions.**

SETTING UP EQUIPMENT

Operator Action	System Action

Check System

1. Plug in Spectra Apheresis System.

2. Turn power switch ON.

   The system will go through a short self-check to ensure that the various power supplies are operating at the correct voltage.

Power up tests in progress.

COBE Spectra (Program Revision __). Press CONTINUE to load tubing set.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- *Load Position
Plasma Valve	-- *Load Position
Collect Valve	-- *Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

   *Refer to Appendix A for an explanation of valve positions.

3. Verify the following:

   - Yellow warning LED is illuminated.
   - "COBE Spectra (Revision __)" is displayed.
   - PAUSE LED is flashing.
   - Cartridge clamps are in load position.
   - Single-Needle Option is installed.
     - Press MENU ON/OFF key.
     - Press 6 to select Configuration.
     - Press ENTER key twice to reach the third configuration screen.
     - Press 3 to select SN.
     - If the next screen says that the Single-Needle Option is not installed, press 1 to install it and press MENU ON/OFF key to remove message.

Operator Action

System Action

- If next screen says that the Single-Needle Option is installed, press MENU ON/OFF key to remove message.

Install Return Flow Controller

If the Return Flow Controller is not already installed on the IV pole, install it following the instructions of the **INSTALLATION OF RETURN FLOW CONTROLLER** section of SECTION 2 – INSTALLATION.

Install Filler

1. Press UNLOCK COVER key.
2. Slide centrifuge cover back.
3. Lower centrifuge door.
4. Rotate centrifuge so centrifuge loading port (with alignment dot) is facing the front. (See Figure 3B-1.)
5. If a single-stage channel filler is in place, remove it as follows:
    - Push filler latching pin (No. 5 in Figure 1-13) toward center of centrifuge and raise filler latch (No. 6 in Figure 1-13).
    - Push filler locking pin (No. 4 in Figure 1-13) toward center of centrifuge and raise filler.
6. Position dual-stage platelet channel filler so dots on centrifuge and filler are aligned. (See Figure 3B-1.)
7. Place filler over centrifuge assembly, and press down until filler locking pin is securely in place.
8. Lower filler latch.
9. Lift up on filler to ensure it is securely in place.
10. Close centrifuge door and cover.
11. Install collect flow path overlay on front panel.

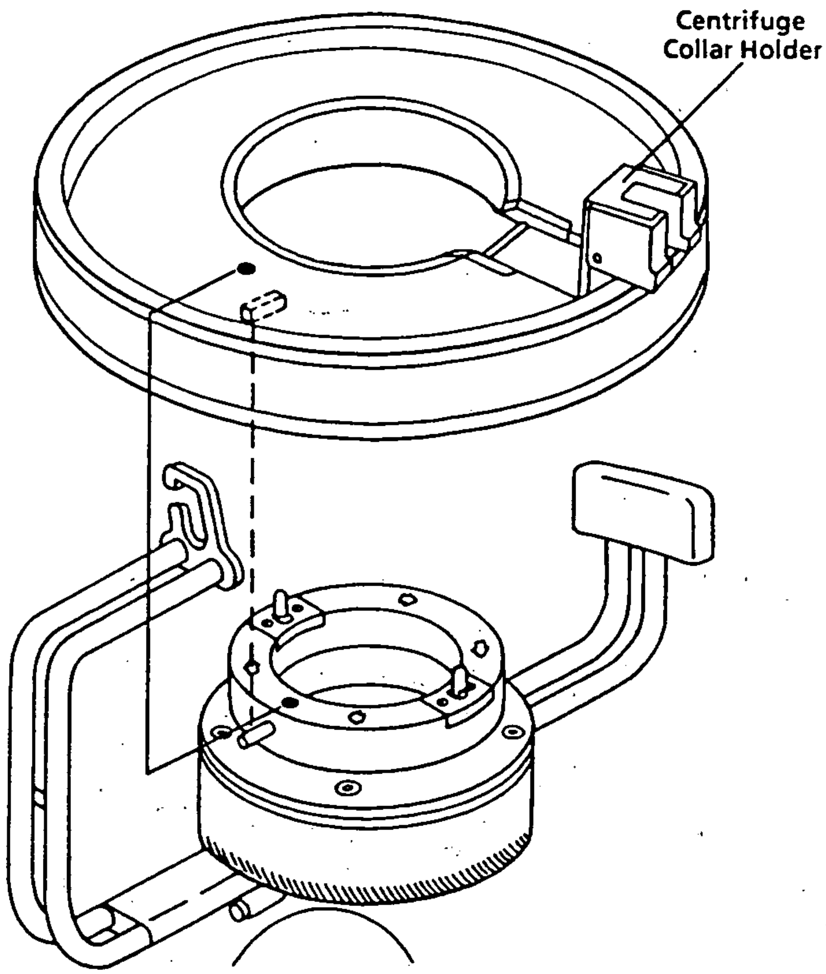

Figure 3B-1. **Correct Filler/Centrifuge Alignment**

Operator Action | System Action

Place Tubing on Front Panel

(See Figure 1-14.)

1. Swing control panel to the side.
2. Peel back cover on disposables package.
3. Place disposables set package on centrifuge cover.
4. Package should be held securely by placing it underneath packaging hook on front panel.

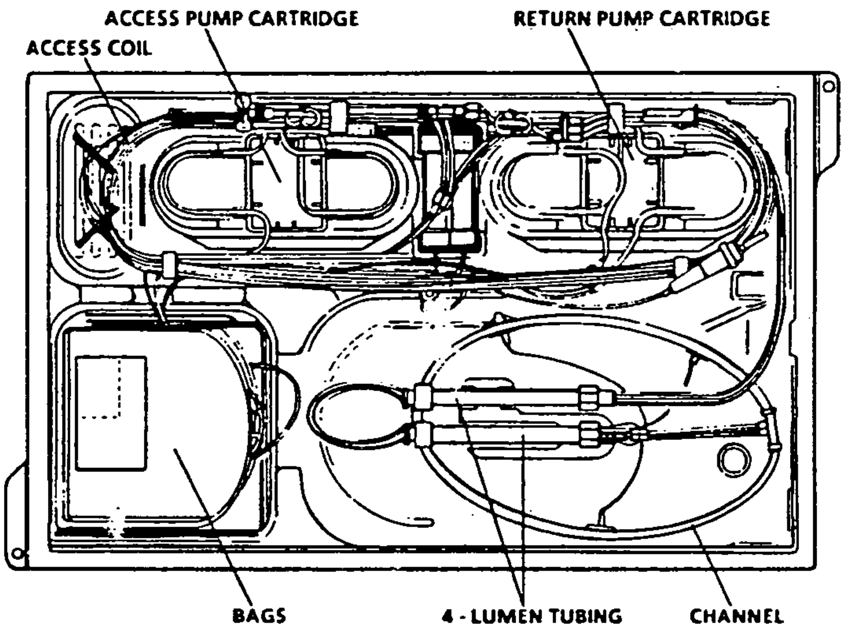

Figure 3B-2. Packaged Tubing Set

5. Remove access coil and remove white paper tape. (See Figure 3B-2.)
   a. Hang access connections on hook on left side of IV pole.
   b. Place access saline line (green-striped) over the top of the system.
6. Hang bags on one hook on the IV pole.

Operator Action	System Action
7. Remove return pump cartridge and snap it into the cartridge clamp between plasma and collect/replace pump. (COBE label on cartridge should be facing up.)	
8. Remove access pump cartridge and snap it into the cartridge clamp between the AC and inlet pumps. (COBE label on cartridge should be facing up.)	
9. Place AC line over top of the system.	
10. Ensure all tubing is clear of pumps and untangled.	
11. Press CONTINUE key to load tubing into pump housings.	Cartridge clamps are retracted and tubing headers are threaded onto pump rotors.

```
Loading pumps.
                                        Load
```

All Pumps	-- 48 ml/min
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Collect Position
Collect Valve	-- Collect Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Time	-- 10 seconds

Operator Action	System Action
12. Verify all four pumps are loaded.	After pumps are loaded, valves automatically open to load position.

13. Put lines in collect/replace and plasma valves.

14. Place sensor in return pressure sensor housing. Turn clockwise to lock in place.

15. Install Collect Concentration Monitor cuvette as follows:

- Pull housing out and turn counterclockwise to lock into the Load (Open) position.
- While holding tubing on both sides of cuvette, slide cuvette into position in collect concentration monitor, being sure that a flat side of the cuvette is parallel to the front panel.

NOTE

Take care not to touch cuvette because finger prints may cause inaccurate platelet readings.

Operator Action	System Action
• Release housing by turning clockwise and gently lower over cuvette to lock into position.	
16. Place RBC line in RBC valve. Ensure line is completely inserted in RBC detector.	
17. Position return and inlet air chambers in air detectors with air chamber filters located below air detector housings. Ensure waste divert lines are toward you.	
18. Put waste lines in waste valve assembly.	
19. Place line in centrifuge pressure sensor housing. Use a "flossing" action to ensure line is completely inserted in pressure sensor.	
20. Place sensor in access pressure sensor housing. Push down and turn clockwise to lock in place.	
21. Position return line in return valve so line runs horizontally through center of valve.	
22. Release four-lumen tubing from package retainers.	

Install Single-Needle Bag

1. Place Return Flow Controller into Load position by turning its flow control hand-crank (Figure 1-16) all the way counter-clockwise to the Load position. (See Figure 1-18.)

2. Load the single-needle bag into the space that Step 1 created at the top of the Return Flow Controller:

NOTE

The single-needle bag is symmetrical and may be loaded with either side up.

   a. Hold bag in your right hand so that the end with the locator hole (Figure 1-12) is pointing toward your left.

   b. Loosely fold the bag in half lengthwise to facilitate its insertion into the Return Flow Controller.

Operator Action	System Action
c. Insert the locator hole end of the bag into the right side of the space made at the top of the Return Flow Controller by Step 1.	
d. Grasp the bag's load tab (Figure 1-12) through the Return Flow Controller's left side access port and place the bag's locator hole over the bag locator pin on the bag mounting plate. (See Figure 1-16.)	
e. Ensure that the bag is lying flat on the plate.	
f. Place the bag's tubes on either side of the bag alignment block.	

Install Channel in Centrifuge

(See Figure 1-13.)

1. Remove channel (Figure 3B-2) from package.
2. Discard package.
3. Press UNLOCK COVER key.
4. Slide centrifuge cover back.
5. Lower centrifuge door.
6. Rotate centrifuge so loading port (No. 8 in Figure 1-13) is open to the front.
7. Ensure that centrifuge collar holder is resting on the outer rim of the filler. (See position of centrifuge collar holder in Figure 3B-1.) If centrifuge collar holder is not resting on the outer rim of the filler, push filler latching pin (No. 5 in Figure 1-13) toward center of centrifuge, raise filler latch (No. 6 in Figure 1-13), and place it on the outer rim.
8. Extend centrifuge loop to full length to ensure four-lumen tubing is not twisted.

Operator Action	System Action

9. Fold channel in half as follows (see Figure 3B-3):

- Hold channel so control chamber is toward you.
- Place hands on either side of control chamber and press sides of channel together.
- Channel should be collapsed with control chamber at one end, forming a banana shape.

CAUTION

Be careful not to stretch the tubes when folding the dual-stage channel.

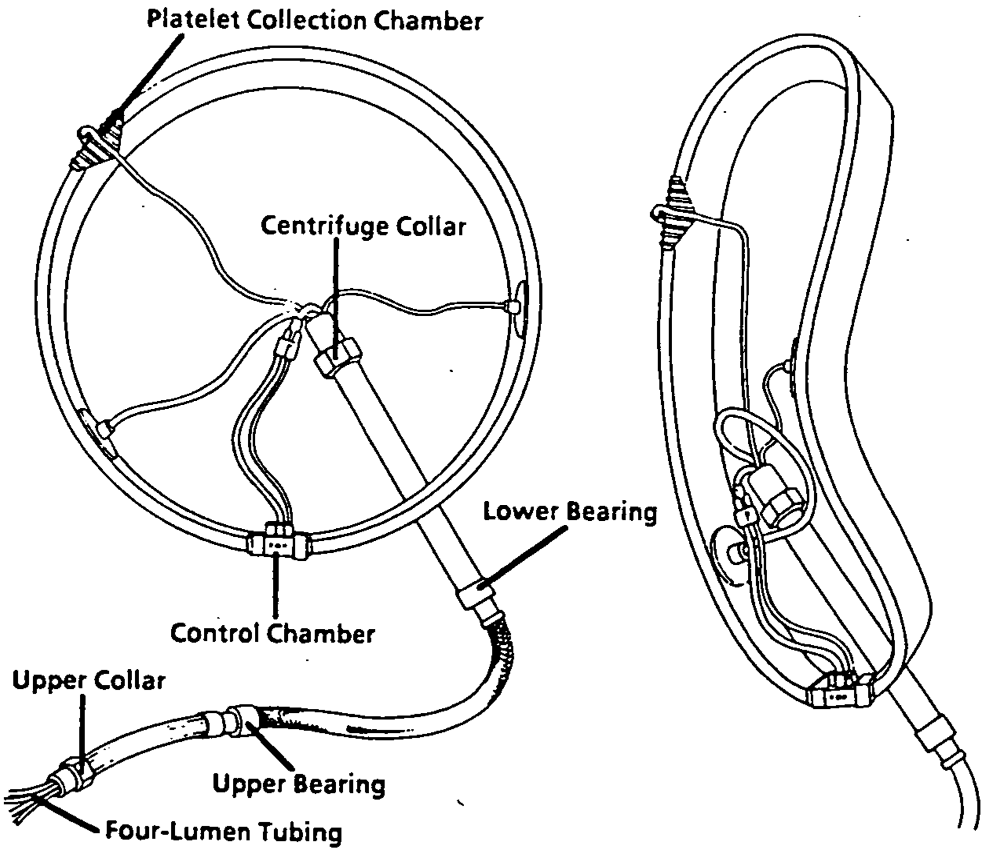

Figure 3B-3. Correctly Folded Dual-Stage Channel

Operator Action	System Action
10. Thread channel through lower loading port (No. 8 in Figure 1-13) and pull it out from the top.	
11. Position channel in correct orientation above filler slots before placing centrifuge collar (Figure 3B-3) into centrifuge collar holder (Figure 3B-1).	
12. Load centrifuge collar into centrifuge collar holder, closing cover over collar.	
13. Lower filler latch into locked position.	
14. Press channel into position, ensuring it is completely loaded in filler. Start at control chamber and work around in both directions toward the collection chamber (Figure 3B-3).	
15. Press tubes into appropriate slots in filler, ensuring all tubes are completely inserted.	
16. Place lower bearing (Figure 3B-3) in lower bearing holder (No.10 in Figure 1-13).	
17. Place upper bearing (Figure 3B-3) in upper bearing holder (No. 11 in Figure 1-13).	
18. Place upper collar (Figure 3B-3) in upper collar holder (No. 12 in Figure 1-13). Ensure that collar is held securely by visually checking that both black sides of holder are equally closed around collar and that an edge between two of the upper collar's six sides is facing out. Be sure that one of the upper collar's six sides is *not* facing out . See Figure 3B-4.	
19. Use a "flossing" action to place four-lumen tubing in exit slot on right side of system. Ensure that the line to the Collect Concentration Monitor is not kinked or twisted.	
20. Rotate centrifuge several times to ensure tubing does not twist and upper bearing remains in place.	

WARNING

Inspect all lines, especially those in the centrifuge and on the front panel, to ensure they are not kinked. Lines that are occluded, or partially ccluded, may lead to the procedure not operating correctly.

21. Close centrifuge door and cover.

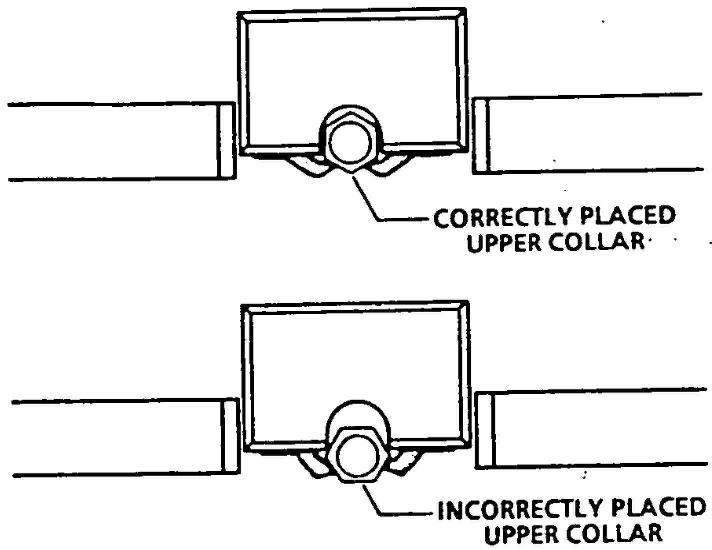

Figure 3B-4. Upper Collar Placement

ELP COLLECTION

Operator Action	System Action

Prime Tubing Set

(See Figure 1-7.)

Note that since the procedure for using the single-needle ELP blood tubing set already makes use of a single-pass prime, the **HOW TO USE AN ALTERNATIVE SINGLE-PASS PRIME PROCEDURE** in SECTION 10 - HELPFUL HINTS only applies to dual-needle ELP procedures.

Select set: 1 = Platelets or ELP,
2 = TPE, 3 = WBC, 4 = RBCX.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

1. After checking all luer connections to ensure that they are secure, press 1 key to select ELP tubing set.

   If you make a mistake and enter the wrong set number:

   - Press the CHANGE MODE key.
   - Press 1 key to select Load Set.
   - Press the 1 key to select the ELP blood tubing set and continue with Step 2.

When the Single-Needle Option is installed, this message is displayed:

Select:
1 = Single needle, 2 = Dual needle.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Operator Action	System Action
2. Press 1 key to select Single needle.	
	When Single-Needle Option is selected in Step 2, this message is displayed.
	Set return flow scale to prime. Press CONTINUE.
	All Pumps -- Stopped Centrifuge -- Stopped Waste Valve -- Load Position Plasma Valve -- Load Position Collect Valve -- Load Position RBC Line Valve -- Open Return Line Valve -- Open
3. Place Return Flow Controller in Prime position by cranking its flow control handcrank (Figure 1-16) clockwise until it can no longer turn. (See "Prime Position" illustration in Figure 1-18.) Do not use excessive force when cranking the handcrank.	
4. Verify that the single-needle bag is pressed flat between the plates of the Return Flow Controller and that the lines leaving the right side of the bag are not kinked or twisted.	
5. Press CONTINUE key.	
	Clamp needle line. Close saline line(s). Press CONTINUE.
	All Pumps -- Stopped Centrifuge -- Stopped Waste Valve -- Load Position Plasma Valve -- Load Position Collect Valve -- Load Position RBC Line Valve -- Open Return Line Valve -- Open
6. Close white pinch clamp on needle line. Close roller clamp on access saline line.	
7. Press CONTINUE key.	

Operator Action	System Action
	Connect Platelet tubing set to fluid containers. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

CAUTION

Use aseptic technique throughout this procedure.

8. Connect AC line to anticoagulant container. Place AC line in AC level detector, ensuring filter is placed below detector.

9. Connect access saline line to plastic spike port on saline container.

CAUTION

Ensure lines are attached to correct fluids:

1. AC line to anticoagulant container

2. Access saline line to normal saline container

Visually verify that fluid is flowing into the access and AC drip chambers.

10. Press CONTINUE key.

Open saline line(s). Press CONTINUE to prime.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

Operator Action	System Action

WARNING

Once fluid has entered the tubing set, do not disturb sensors in pressure sensor housings because this will prevent transducers from monitoring pressures accurately. (See SECTION 12 - RECOVERY PROCEDURES for information on how to load pressure sensors with fluid in the tubing set.)

11. Open access saline roller clamp.

12. Press CONTINUE key to prime tubing set.

If Spectra system was not turned off after the last procedure, it will go through a short self-check before beginning Prime.

> Power up tests in progress.

NOTE

Cuvette should not be disturbed once priming begins because the Collect Concentration Monitor is calibrated during Prime mode.

> Priming anticoagulant line.
> (Platelet Set) Prime

AC Pump	-- 100 ml/min
Inlet Pump	-- 150 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Inlet Divert Position
Plasma Valve	-- Collect Position
Collect Valve	-- Collect Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- 30 ml AC
Approximate Time	-- 18 seconds

13. Move bags to correct positions* on IV pole as follows:

●	●	●	●	●	●	●
AC	Inlet Saline	Waste	Single Needle**	Plasma	ELP Collect	ELP Collect

* Because of the space occupied by the Return Flow Controller, some bags, for example, the AC and inlet saline bags, will need to share the front and back of the same hook.

** Installed in Return Flow Controller

Operator Action	System Action

14. Close slide clamp between ELP collect bags. (Platelet concentrate should be collected into one bag for optimal 5-day storage. If collect volume is over 300 ml at end of procedure, transfer about one-half of platelet concentrate to the second ELP collect bag.)

15. Donor data can be entered before tubing set is primed, during Prime mode, or after priming is complete:

   a. To enter donor data before Prime mode, select set type (1 = Platelets or ELP) and press MENU ON/OFF key. Continue with Step 15d.

   b. To enter donor data during Prime mode, press MENU ON/OFF key. Continue with Step 15d.

   c. To enter donor data after priming is complete, continue with Step 16.

   d. Press 1 key to select "Data Entry." (Refer to following section, **Enter Donor Data**, for instructions on how to enter donor information.)

Priming inlet line and air chamber.
(Platelet Set) Prime

Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Inlet Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Volume	-- Fluid in Inlet Air Chamber Plus 40 ml
Approximate Time	-- 57 seconds

This step pumps saline through the access saline line, inlet line, and inlet air chamber. To prime the waste line, saline flows for a short time after fluid is detected in inlet air chamber.

Operator Action	System Action

Testing sensors, valves, and pumps.
Prime

AC Pump	-- Stopped
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Varies Flow Rate
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Time	-- 51 seconds

The various valves and pumps change position as the system does a series of self-checks to ensure front panel components have been loaded correctly.

Priming centrifuge channel.
Prime

AC Pump	-- Stopped
Inlet Pump	-- 100 ml/min
Plasma Pump	-- 3(ml/min
Collect Pump	-- Stopped
Centrifuge	-- 400 rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- 182 ml Inlet
Approximate Time	-- 110 seconds

Priming centrifuge channel.
Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/min
Plasma Pump	-- 20 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- 20 ml Inlet
Approximate Time	-- 10 seconds

Operator Action	System Action

Priming centrifuge channel.
Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/min
Plasma Pump	- 20 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- 20 ml Inlet
Approximate Time	-- 10 seconds

Priming centrifuge channel.
Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/min
Plasma Pump	-- 10 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 1600 rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- 20 ml Inlet
Approximate Time	-- 10 seconds

Testing sensors, valves, and pumps.
Prime

AC Pump	-- Stopped
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Stopped
Collect Pump	-- Varies Flow Rate
Centrifuge	-- 1600 rpm
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Time	-- 12 seconds

Operator Action | **System Action**

> Priming return air chamber.
>
> Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- 15 ml/min
Centrifuge	-- 2000 rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- Fluid in Return Air Chamber Plus 25 ml
Approximate Time	-- 48 seconds

> Priming return lines.
>
> Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- 2400 rpm
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Varies Position
Approximate Volume	-- 50 ml Inlet
Approximate Time	-- 25 seconds

The air from the return line is accumulated in the inlet air chamber and then diverted to the waste bag.

> Testing sensors, valves, and pumps.
>
> Prime

All Pumps	-- Vary Flow Rate
Centrifuge	-- Varies
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Varies Position
RBC Line Valve	-- Varies Position
Return Line Valve	-- Varies Position
Approximate Time	-- 60 seconds

The various valves and pumps change position as the system removes air from channel and does a series of self-checks.

Operator Action	System Action
	Priming single needle bag. Prime

All Pumps	-- Vary Flow Rate
Centrifuge	-- Varies
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Varies Position
Return Line Valve	-- Varies Position

Prime donor connection.
Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

16. Open white needle pinch clamp.

17. Ensure white access pinch clamp near access line connection to "Y" manifold is open. Allow saline to fill luer lock connection, "Y" arm, and needle by gravity. Close white needle pinch clamp.

18. Press CONTINUE key.

Close access saline line. Clamp access line. Press CONTINUE to test AC ratio.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Inlet Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

19. Use roller clamp to close green-striped access saline line, close white access pinch clamp, and press CONTINUE to test the AC ratio.

Operator Action	System Action
	Testing AC ratio. Prime

AC Pump	-- Varies Flow Rate
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Inlet Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Time	-- 11 seconds

The AC and inlet pumps change flow rates as the system does a series of self-checks.

WARNING: Do not connect donor/patient before running Alarm Tests. CONTINUE.

20. Press CONTINUE key to clear this warning from screen.

Perform alarm tests (YES/NO)?

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Time	-- 9 seconds

21. Press YES key to run semiautomatic alarm tests. Refer to SECTION 9 – DIAGNOSTICS for **ALARM TESTS** procedure.

At this point the Spectra system provides an opportunity to verify that key alarm systems are fully operational. Alarm tests will check operation of access pressure sensor, return air detector, return pressure sensor, fluid leak detector, and centrifuge door and cover safety system.

22. Continue with **Enter Donor Data** steps.

Operator Action | **System Action**

Ent r Donor Data

The Spectra system will customize platelet collections by using donor data to calculate pump flow rates, centrifuge speed, collect volume, inlet/anticoagulant ratio, and procedure time.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Select sex: 1 = Male, 2 = Female.
(ENTER = Male)

1. Enter donor sex:

- Press 1 if male.
- Press 2 if female.
- Press ENTER for default (data in parentheses).

(English units - enter feet):

Enter height,
in feet: {0} , and/or inches: 0

(Range: 1 to 7 feet)

2. Enter donor height:

Feet and Inches	Inches	Centimeters
_ feet plus ENTER then _ inches plus ENTER	ENTER then _ inches plus ENTER	_ centimeters plus ENTER
Range: 1-7 ft	Range: 12-84 in.	Range: 30-220 cm

(English units):

Enter weight,
in pounds: {0}

(Range: 10 to 500 lbs)

3. Enter donor weight in pounds (or kilograms). Then press ENTER key.

Operator Action	System Action
	Total blood volume = _____ ml. (_____ in, _____ lbs, Female). OK (YES/NO)?
	To confirm input, the Spectra system displays estimated total blood volume and donor data. Total blood volume is calculated from donor data entered into system. The second line of display reviews data input: height, weight, and sex.
4. Confirm donor data input: • Press NO one time = weight entry display. Press NO two times = height entry display. Press NO three times = sex entry display. • Press YES = next display: hematocrit entry.	
	Enter hematocrit (%): {41} (Range: 10% to 70%)
5. Enter hematocrit as a whole number. (Decimal point is not required.) Then press ENTER.	The Spectra system will use default values of 45% for males and 41% for females. **NOTE** If default values for hematocrit are used, inlet:AC ratio will be based on default value rather than on donor hematocrit and, hence, may not yield best collection performance.
	Enter platelet pre-count, in cells/microliter: {250} x 1000 (Range: 1 to 2,000 = 1,000 to 2,000,000/ul)
6. Enter donor platelet pre-count in thousands per microliter. Then press ENTER.	The Spectra system will use a default value of 250,000/ul. **NOTE** If default value for platelet pre-count is used, yield and concentration calculations will be based on default value and may not give accurate values for predicted yield and concentration.

Operator Action	System Action
	1 = no plasma, 2 = collect plasma. (ENTER = no plasma)
7. The Spectra system allows plasma to be concurrently collected with platelets: a. Press 1 or ENTER key if you do not want to concurrently collect plasma. b. Press 2 if you want to concurrently collect plasma.	
	Yield = __.__E11, collect = _____, conc = __,___, plasma = ___, time = ___ min. OK (YES/NO)?
	The Spectra system uses donor data (entered by the operator) and microprocessor algorithms to calculate and show the following information on the platelet yield display: • Platelet yield displayed to the eleventh power (for example, 4E11 = 4 x 10^{11}). • Collect volume displayed in milliliters. • Platelet concentration in collect bag displayed in thousands per microliter (x 1000). (Default value is 1,400,000 per microliter.) • Plasma volume in milliliters. • Procedure time displayed in minutes. (Default value is 100 minutes.) **NOTE** Platelet concentrations above 2,100,000/ microliter have not been validated for extended storage.
8. Approve platelet collection values: • Press YES = exit donor data entry displays and continue to **Connect Donor** section • Press NO = next display: *platelet settings message*	
	Change: 1 = run time, 2 = inlet flow, 3 = collect volume, 4 = conc., 5 = plasma.

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Operator Action	System Action
IMPORTANT: When one value is changed, this will affect other values. For example, increasing the inlet flow rate will increase the AC infusion rate back to the donor. (See Tables 3B-1 and 3B-2 for other examples of how changing one platelet collection value affects others.)	

Table 3B-1. Effect Changing One Platelet Collection Value Has on Others When Plasma Is Not Being Collected or a Fixed Plasma Volume Has Been Entered

Changed Value	Affected Value
Run Time	Platelet Yield Inlet Volume Platelet Collect Volume AC Volume
Inlet Flow	AC Infusion Rate Platelet Yield Inlet Volume Platelet Collect Volume AC Volume
Platelet Collect Volume	Increased Volume = Lower Platelet Concentration and Slight Increase in Platelet Yield Inlet Volume AC Volume Inlet Flow Decreased Volume = Higher Platelet Concentration and Slight Decrease in Platelet Yield Inlet Volume AC Volume Inlet Flow
Platelet Collect Concentration	Increased Platelet Concentration = Lower Platelet Collect Volume and Slight Decrease in Platelet Yield Inlet Volume AC Volume Inlet Flow Decreased Platelet Concentration = Higher Platelet Collect Volume and Slight Increase in Platelet Yield Inlet Volume AC Volume Inlet Flow

Table 3B-2. Effect Changing One Platelet Collection Value Has on Others If "Collect Plasma" Is Selected in Step 7

Changed Value	Affected Value
Run Time	Platelet Yield Inlet Volume Platelet Collect Volume Plasma Volume AC Volume
Inlet Flow	AC Infusion Rate Platelet Yield Inlet Volume Platelet Collect Volume AC Volume Plasma Volume
Platelet Collect Volume	Increased Volume = Lower Platelet Concentration and Lower Plasma Volume Decreased Volume = Higher Platelet Concentration and Higher Plasma Volume
Platelet Collect Concentration	Increased Platelet Concentration = Lower Platelet Collect Volume and Higher Plasma Volume Decreased Platelet Concentration = Higher Platelet Collect Volume and Lower Plasma Volume
Plasma Volume	Once plasma volume has been changed, use Table 3B-1.

9. Select platelet collection value to be changed:

- Press 1 = braces around run time
- Press 2 = braces around inlet flow rate
- Press 3 = braces around collect volume
- Press 4 = braces around concentration
- Press 5 = braces around plasma volume
- Press 9 = redisplays *concurrent plasma collection selection message* (precedes Step 7 above)

Operator Action | System Action

Yield = __.__E11, collect = _____, conc = __,___, plasma = ___, time = ___ min. Inlet = ___.__

10. Using arrow keys, change selected value. The up arrow key increases the value, and the down arrow key decreases it. Affected value(s) will also be changed. When satisfied that changed and affected values are appropriate, press ENTER to return to *platelet yield message* (follows Step 7 above). Press CLEAR key to return to *platelet settings message* (follows Step 8 above).

When changing platelet and plasma collection values, the following value ranges are allowed for changed values.

Changed Value	Allowed Range
Run Time	10-999 min
Inlet Flow	15-50 ml/min
Platelet Collect Volume	10-9999 ml
Platelet Collect Concentration	100-8,000 (100,000-8,000,000/ul)
Plasma Volume	0-999 ml*

* Maximum allowable plasma volume can be increased to 1500 ml via the Total Plasma Collect Volume Entry Configuration. (See Configuration Selection Messages in Appendix A.)

11. Follow the steps below to monitor the effect that increasing the inlet flow rate has on the AC infusion rate and to verify that the AC infusion rate does not exceed the prescribed limit for the donor:

a. Press MENU ON/OFF key.

1 = Data Entry, 2 = Pressure Display, 3 = CCM, 4 = Air Remove, 5 = Strobe, 6 = Config., 7 = SN.

b. Press 1 key to select "Data Entry."

Operator Action	System Action
	1 = Change procedure, 2 = Change donor information, 3 = Run results, 4 = AC data.
c. Press 4 key to display the *AC status message*.	
	AC infusion rate: 0.8 ml/min/liter TBV. ml AC in bags: collect:_____, plasma:_______.
d. Press MENU ON/OFF key a second time to redisplay the *platelet yield message* (follows Step 7 above).	

Connect Donor

WARNING

Before connecting donor, check access and return lines for air. If air is present in these lines, do not connect donor. Remove air before starting procedure.

Close saline line(s).
Connect donor. Press CONTINUE to Run.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

1. Close roller clamp on access saline line. Verify that white pinch clamp on needle is closed.

2. Perform venipuncture at needle site.

WARNING

The extended storage of platelets at 22°C requires strict awareness of any possible sources of extrinsic contamination. Rigorous attention should be paid to proper venipuncture site selection and decontamination.

Operator Action	System Action
3. Open white pinch clamp on needle. Verify that white pinch clamp on access line is open.	
4. To improve antecubital access flow, maintain a cuff pressure of between 10 and 20 mmHg on the access/return arm.	

Start Run Mode

1. Press CONTINUE key to start system in Run mode.

All pumps will start and centrifuge speed will increase based on parameters preset by donor data and Spectra algorithms.

AC	Inlet	Plasma	Collect Replace	Inlet AC Ratio	Spin RPM
_._	___._	___._	___._	___._	_____

Diverting prime saline.

AC Pump	-- ___._ ml/min
Inlet Pump	-- ___._ ml/min
Plasma Pump	-- ___._ ml/min
Collect Pump	-- ___._ ml/min
Ratio	-- _ : 1
Centrifuge	-- ______ rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

NOTE

It is normal that a small amount of red cells may be diverted to the waste bag when prime saline is diverted.

2a. If you want to divert the prime saline to the waste bag, continue with Step 3.

OR

2b. If you do not want to divert the prime saline to the waste bag and, instead, want to return it to the donor, follow these steps:

- Press the CHANGE MODE key.
- Press 3 key to select Run.
- Press CONTINUE key.
- Continue with Step 3.

Operator Action	System Action
	Set return flow scale to ___. Press CONTINUE.

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- ______ rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

Audio : Operator-attention alarm sounds.

All pump speeds, the centrifuge speed, and plasma and collect valve positions are set by alogrithms.

3. Note the number on the screen above. Turn flow control handcrank on Return Flow Controller (Figure 1-16) counterclockwise until the return flow indicator points to that number on the return flow scale (Figure 1-18).

4. Press CONTINUE key.

When the single-needle return phase is reached, the Return Flow Controller will apply the appropriate pressure to the single-needle bag to return the blood components withdrawn during the single-needle draw phase back to the donor at the correct flow rate.

The Spectra system automatically establishes red cell/plasma interface and waits until at least 200 ml of inlet volume have been processed before collecting platelets that have entered the second stage of the dual-stage channel.

If concurrent plasma collection was selected in Step 7 of the **Enter Donor Data** mode, the Spectra system will wait until at least 500 ml of inlet volume have been processed and then place the plasma valve in the collect position and begin collecting plasma, also from the second stage of the dual-stage channel.

Operator Action

System Action

During single-needle procedures, if you or the Spectra control program command the plasma or collect valve to move, this movement will not take place until the latter portion of each return phase when the return pressure is low. If you set a target volume of plasma, the single-needle procedure will proceed as follows:

- Return plasma (saline) will be returned to the donor until the inlet volume exceeds 500 ml.

- At the end of the next single-needle return phase (or at the end of the next return phase after selecting a target volume of plasma to be collected), the Spectra control program will switch the plasma valve to the collect position.

- When the volume of plasma collected equals or exceeds the target volume, the Spectra control program will switch the plasma valve back to the return position at the end of the next single-needle return phase.

- For single-needle ELP procedures, the Spectra control program limits the average inlet flow rate to 50 ml/min and the instantaneous inlet flow rate to 150 ml/min.

The Spectra system displays pump flow rates, anticoagulant ratio, centrifuge rpm, accumulated volumes processed by each pump, procedure time (in minutes), and procedure type. For single-needle procedures, average flow rates are displayed. Step 6 below explains how to display instantaneous single-needle flow rates.

AC	Inlet	Plasma	Collect Replace	Inlet : AC Ratio	Spin RPM
__.__	___.__	___.__	___.__	___.__	____
___	___	___	___	___	SNPLTC
AC	Inlet	Plasma	Collect Replace	Time Min	Procedure

Operator Action

System Action

NOTE

If centrifuge step down is enabled, refer to *centrifuge step down selection message* in APPENDIX A.

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- _ : 1
Centrifuge	-- ______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

During a draw phase of a single-needle platelet collect procedure, a "D" will appear in the upper left-hand corner of the display screen. During a return phase, an "R" will appear.

5. To monitor instantaneous draw phase flow rates:

   a. Press MENU ON/OFF key.

1 = Data Entry, 2 = Pressure Display, 3 = CCM, 4 = Air Remove, 5 = Strobe, 6 = Config., 7 = SN.

   b. Press 7 key to select "SN" and display the *single-needle instantaneous screen.*

   c. Press MENU ON/OFF key to leave the single-needle instantaneous screen and redisplay the Spectra *SNPLTC procedure screen* above.

6. If you have already entered the Run mode before you decide to concurrently collect plasma, you can do so at this point by following these steps:

   a. Press TARGET key to display current end-of-run target values.

   b. Press PLASMA VOLUME key.

   c. Enter volume of plasma you want to collect.

Operator Action	System Action
d. Press TARGET key a second time to redisplay the screen immediately above with its current actual volume values.	
	Run mode continues until target values are reached. Values that have exceeded their limits will be flashing. There are audio and visual warnings when Run mode is complete.

```
End of Run:  1 = Rinseback, 2 = Continue Run.
____   ____   ____   ____   ____   SNPL TC
```

AC	Inlet	Plasma	Collect Replace	Time Min	Procedure

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- ______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Operator Action	System Action
7. Press 2 key to continue Run mode. (To start Rinseback mode, press 1 key and skip to **Start Rinseback Mode** section.)	If no selection is made, a shutdown alarm will occur after 10 minutes and the pumps will stop.

```
Increase flashing target limits.
____   _____   _____   _____   _____   Target
```

AC	Inlet	Plasma	Collect Replace	Time Min	Procedure

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- ______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Operator Action	System Action
8. Select flashing target value on bottom row of display.	Inlet volume processed and time elapsed are only values that flash.
9. To increase inlet volume or time, press appropriate key.	

Operator Action	System Action
10. Enter new target value on numeric keypad. Then press ENTER.	Run mode continues until target values are reached. There are audio and visual warnings when Run mode is complete.

```
End of Run:  1 = Rinseback, 2 = Continue Run.
____   ____   ____   ____   ____   SNPLTC
```

AC	Inlet	Plasma	Collect Replace	Time Min	Procedure

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- _______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Start Rinseback Mode

1. Press 1 key to start Rinseback mode.

If no selection is made, a shutdown alarm will occur after 10 minutes.

```
Clamp access.  Open access saline.
Press CONTINUE to Rinseback.
```

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- _______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

2. Close white pinch clamp on the access line between the "Y" manifold and the access manifold. Open roller clamp on green-striped access saline line to allow saline to enter the system.

3. Press CONTINUE key to start Rinseback and continue with Step 4.

Operator Action

System Action

Rinseback: Collecting. Rinse.

AC Pump	-- Stopped
Inlet Pump	-- ___._.ml/min
Plasma Pump	-- ___._ ml/min
Collect Pump	-- ___._ ml/min
Centrifuge	-- ______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 50 ml inlet volume
Approximate Time	-- 30 seconds

The Spectra system will continue to collect platelets during first few minutes of Rinseback mode until CCM shows the concentration is too low to collect or until 50 milliliters of inlet volume have been processed.

Rinseback: Collecting step is skipped if collect valve is in return position. For example, during a red cell spillover, CCM moves collect valve automatically to return position.

Clamp and disconnect collection bags. Press CLEAR.

AC Pump	-- Stopped
Inlet Pump	-- 50.0.ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

NOTE

If the average inlet flow was higher than 50 ml/min during the Run mode, the inlet pump will run at the higher rate.

Operator Action	System Action

4. **IMPORTANT**: Clamp or seal collect line above and below luer connection and remove platelet product bags. If more than 300 ml of platelet concentrate has been collected, first store about one-half in each platelet product bag. If platelet concentrate volume is less than 300 ml, store in one bag. For the steps to follow to collect a double-platelet product, see **HOW TO PREPARE A DOUBLE-PLATELET PRODUCT** in SECTION 10 - HELPFUL HINTS.

   If concurrent plasma has been collected, clamp or seal plasma line and remove plasma product bag.

5. Press CLEAR to continue Rinseback.

Rinseback: Returning RBCs.
Rinse.

AC Pump	-- Stopped
Inlet Pump	-- 50.0.ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 90 ml Inlet
Approximate Time	-- 108 seconds

Red blood cell line is only flow back to donor during this step.

NOTE

If the average inlet flow was higher than 50 ml/min during the Run mode, the inlet pump will run at the higher rate.

Operator Action	System Action

System Action

Rinseback: Recirculating.
Rinse.

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma Pump	-- 150.0 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Recirculate Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Volume	-- 225 ml Plasma
Approximate Time	-- 90 seconds

The Spectra system closes return line valve and flushes red cells off channel wall by recirculating saline through channel at high speed.

NOTE

No flow to or from donor during this step.

Rinseback: Evacuating channel.
Rinse.

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma Pump	-- 50.0 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 100 ml Plasma
Approximate Time	-- 150 seconds

The Spectra system opens return line valve so free red cells can be returned to donor. Channel is collapsed to reduce extracorporeal blood volume.

Operator Action	System Action

> Rinseback: Rinsing channel.
> Rinse.

AC Pump	-- Stopped
Inlet Pump	-- 50.0 ml/min
Plasma Pump	-- 50.0 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 58 ml Inlet
Approximate Time	-- 70 seconds

The Spectra system allows additional saline to enter channel to flush final red cells back to donor.

NOTE

If the average inlet flow was higher than 50 ml/min during the Run mode, the inlet pump will run at the higher rate.

Disconnect Donor

NOTE

Before disconnecting donor, verify that platelet and plasma product bags are clamped or sealed and removed, and that the line below the collect bag luer is clamped.

> Rinseback completed. Disconnect return line. Close fluids. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed

1. When Rinseback mode is completed, close white pinch clamp on access/return needle. Disconnect needle. Close roller clamp on green-striped access saline line.

2. To ensure that fluids do not leak when disposables are removed, close slide clamps at the collect and plasma lines and, when possible, connect access/return line to collect line (where collect bags were disconnected).

Operator Action	System Action
3. Press CONTINUE key.	

Final values. Press CONTINUE to unload.

AC	Inlet	Plasma	Collect / Replace	Time Min	Procedure
___	___	___	___	___	___

All Pumps -- Stopped
Centrifuge -- Stopped
Waste Valve -- Load Position
Plasma Valve -- Load Position
Collect Valve -- Load Position
RBC Line Valve -- Open
Return Line Valve -- Open

4. Record on donor records final volumes processed during procedure.

REMOVING ELP DISPOSABLES

Operator Action	System Action
(See Figure 1-13.)	
1. Place end of access/return line in appropriate biohazard disposal container.	
2. Press UNLOCK COVER key.	
3. Slide centrifuge cover back.	
4. Lower centrifuge door.	
5. Remove four-lumen tubing from exit slot on right side of system.	
6. Remove collar from upper collar holder.	
7. Remove upper bearing from upper bearing holder.	
8. Remove lower bearing from lower bearing holder.	
9. Push filler latching pin toward center of centrifuge and raise filler latch.	
10. Pull tubes from slots in filler.	
11. Pull channel from filler.	
12. Open hinged cover on centrifuge collar holder and remove collar.	
13. Raise channel above filler.	
14. Fold channel in half and pull through loading port.	
15. Discard channel in appropriate biohazard disposal container. (Channel will still be connected to tubing.)	
16. Close centrifuge door and cover.	

Operator Action	System Action
17. Remove lines from the following: • Collect and plasma valves • Return pressure sensor • Waste divert valve • RBC line valve • Collect concentration monitor • Return and inlet air detectors • Centrifuge pressure sensor • Access pressure sensor • Return line valve • Anticoagulant level detector	
18. Press CONTINUE key to unload pumps.	Unloading pumps. Unload All Pumps -- 48 ml/min Centrifuge -- Stopped Waste Valve -- Load Position Plasma Valve -- Load Position Collect Valve -- Load Position RBC Line Valve -- Open Return Line Valve -- Open Approximate Time -- 7 seconds
19. Remove lines from cartridge clamps (press clamps up to release pump cartridges).	
20. Remove access/return needle from tubing set and place in appropriate needle disposal container.	
21. Remove fluid containers and waste bag from the Spectra system. Remove single-needle bag from Return Flow Controller. Place fluid containers, waste bag, and single-needle bag in appropriate biohazard disposal container along with tubing.	COBE Spectra (Revision __). Press CONTINUE to load tubing set.

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4a-Platelet Operation

SECTION 4A - PLATELET DUAL-NEEDLE OPERATION

This dual-needle procedure is intended for use when a Platelet blood tubing set is used to collect donor platelets for storage up to 24 hours. See SECTION 4B – PLATELET SINGLE-NEEDLE OPERATION for Platelet single-needle procedure.

REQUIRED EQUIPMENT AND SUPPLIES

DUAL- AND SINGLE-NEEDLE PROCEDURES

- COBE Spectra™ Apheresis System
- Dual-stage platelet channel filler
- Collect flow path overlay
- Disposable Platelet blood tubing set (Catalog Number 777004-000)
- Anticoagulant (ACD-A – each 100 ml contains: 2.2 g sodium citrate hydrous, 730 mg citric acid anhydrous, and 2.45 g dextrose hydrous)
- 0.9% sodium chloride for injection (1000 ml). When only single-port saline containers are available and/or hypersensitivity reactions associated with ethylene oxide sterilization must be avoided, see **HOW TO USE AN ALTERNATIVE SINGLE-PASS PRIME PROCEDURE** in SECTION 10 – HELPFUL HINTS.
- Forceps or hemostats

DUAL-NEEDLE PROCEDURES ONLY

- Two needles

NOTE

During Dual-Needle Platelet collections, the COBE Spectra Apheresis System collects leukocyte-poor platelet concentrate with an average WBC content of 4.9 X 10^5 per product.[1] The actual WBC counts may increase depending upon

- Limitations of WBC counting technique
- Spillovers during the procedure
- Concurrent plasma collection

[1] Dzik, W.H., Tagosta, A., and Cusack, W.F., Flow Cytometric Method for Counting Very Low Numbers of Leukocytes in Platelet Products. *Vox Sang* 1990; 59: 153-59.

Operator Action	System Action

Check System

1. Plug in Spectra Apheresis System.

2. Turn power switch ON.

The system will go through a short self-check to ensure that the various power supplies are operating at the correct voltage.

Power up tests in progress.

COBE Spectra (Program Revision __). Press CONTINUE to load tubing set.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- *Load Position
Plasma Valve	-- *Load Position
Collect Valve	-- *Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

*Refer to Appendix A for an explanation of valve positions.

3. Verify the following:

- Yellow warning LED is illuminated.
- "COBE Spectra (Revision __)" is displayed.
- PAUSE LED is flashing.
- Cartridge clamps are in load position.

Install Filler

1. Press UNLOCK COVER key.

2. Slide centrifuge cover back.

3. Lower centrifuge door.

4. Rotate centrifuge so centrifuge loading port (with alignment dot) is facing the front. (See Figure 4A-1.)

5. If a single-stage channel filler is in place, remove it as follows:

- Push filler latching pin (No. 5 in Figure 1-13) toward center of centrifuge and raise filler latch (No. 6 in Figure 1-13).

Operator Action | **System Action**

- Push filler locking pin (No. 4 in Figure 1-13) toward center of centrifuge and raise filler.

6. Position dual-stage platelet channel filler so dots on centrifuge and filler are aligned. (See Figure 4A-1.)

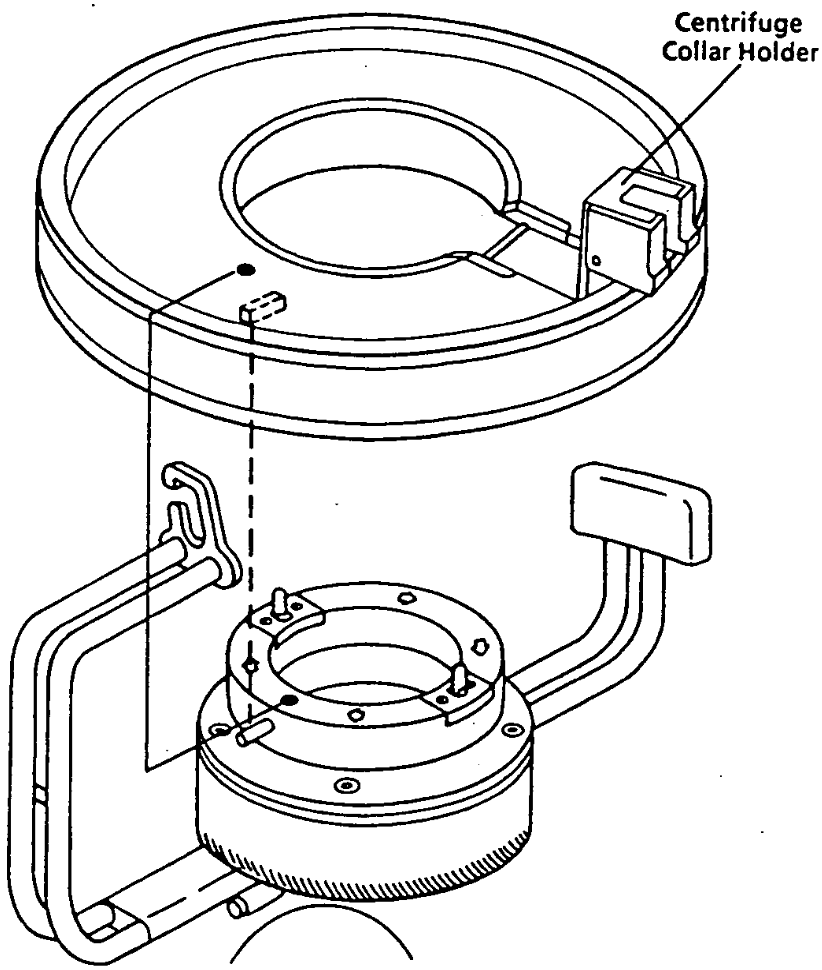

Figure 4A-1. Correct Filler/Centrifuge Alignment

7. Place filler over centrifuge assembly, and press down until filler locking pin is securely in place.

8. Lower filler latch.

Operator Action	System Action
9. Lift up on filler to ensure it is securely in place.	
10. Close centrifuge door and cover.	
11. Install collect flow path overlay on front panel.	

SETTING UP PLATELET DISPOSABLES

Operator Action	System Action

Place Tubing on Front Panel

(See Figure 1-14.)

1. Swing control panel to the side.
2. Peel back cover on disposables package.
3. Place disposables set package on centrifuge cover.
4. Package should be held securely by placing it underneath packaging hook on front panel.
5. Remove inlet line coil and remove white paper tapes. (See Figure 4A-2.)

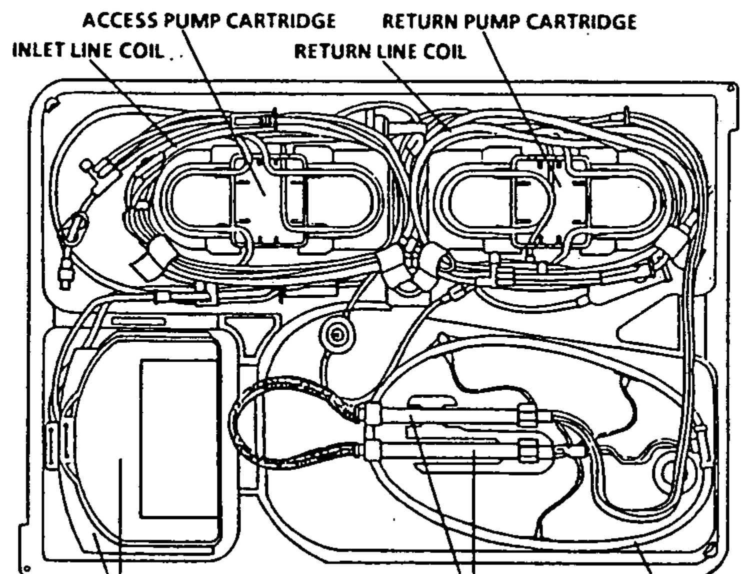

Figure 4A-2. Packaged Tubing Set

a. Hang donor/patient connection on hook on left side of IV pole. (For identification purposes, the three lines attached to this connection are taped together with red tape until they reach the front panel.)

b. Place access saline line (green striped) over the top of the system.

Operator Action	System Action
6. Remove return line coil and remove white paper tapes. (See Figure 4A-2.)	
a. Hang donor/patient connection on hook on left side of IV pole. (For identification purposes, the two lines attached to this connection are taped together with blue tape until they reach the front panel.)	
b. Place return saline line over the top of the system.	
7. Hang bags on one hook on the IV pole.	
8. Remove return pump cartridge and snap it into the cartridge clamp between plasma and collect/replace pump. (COBE label on cartridge should be facing up.)	
9. Remove access pump cartridge and snap it into the cartridge clamp between the AC and inlet pumps. (COBE label on cartridge should be facing up.)	
10. Place AC line over top of the system.	
11. Ensure that all tubing is clear of pumps and untangled.	
12. Press CONTINUE key to load tubing into pump housings.	Cartridge clamps are retracted and tubing headers are threaded onto pump rotors.

Operator Action	System Action
	Loading pumps. Load

All Pumps	-- 48 ml/min
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Collect Position
Collect Valve	-- Collect Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Time	-- 10 seconds

13. Verify all four pumps are loaded.

After pumps are loaded, valves automatically open to load position.

14. Put lines in collect/replace and plasma valves.

15. Place sensor in return pressure sensor housing. Press down and turn clockwise to lock in place.

16. Install Collect Concentration Monitor cuvette as follows:

   - Pull housing out and turn counterclockwise to lock into the Load (Open) position.

   - While holding tubing on both sides of cuvette, slide cuvette into position in collect concentration monitor, being sure that a flat side of the cuvette is parallel to the front panel.

NOTE

Take care not to touch cuvette because finger prints may cause inaccurate platelet readings.

   - Release housing by turning clockwise and gently lower over cuvette to lock into position.

17. Place RBC line in RBC valve. Ensure line is completely inserted in RBC detector.

18. Position return and inlet air chambers in air detectors with air chamber filters located below air detector housings. Ensure waste divert lines are toward you.

19. Put waste lines in waste valve assembly.

Operator Action	System Action
20. Place line in centrifuge pressure sensor housing. Use a "flossing" action to ensure line is completely inserted in pressure sensor.	
21. Place sensor in access pressure sensor housing. Push down and turn clockwise to lock in place.	
22. Position return line in return valve so line runs horizontally through center of valve.	
23. Using aseptic technique, connect male/female luer lock (No. 29 above return air chamber in Figure 1-8). **Secure but do not overtighten connection.**	
24. Release four-lumen tubing from package retainers.	

Install Channel in Centrifuge

(See Figure 1-13.)

1. Remove channel (Figure 4A-2) from package.
2. Discard package.
3. Press UNLOCK COVER key.
4. Slide centrifuge cover back.
5. Lower centrifuge door.
6. Rotate centrifuge so loading port (No. 8 in Figure 1-13) is open to the front.
7. Ensure that centrifuge collar holder is resting on the outer rim of the filler. (See position of centrifuge collar holder in Figure 4A-1.) If centrifuge collar holder is not resting on the outer rim of the filler, push filler latching pin (No. 5 in Figure 1-13) toward center of centrifuge, raise filler latch (No. 6 in Figure 1-13), and place it on the outer rim.
8. Extend centrifuge loop to full length to ensure four-lumen tubing is not twisted.
9. Fold channel in half as follows (see Figure 4A-3):

Operator Action | System Action

- Hold channel so control chamber is toward you.
- Place hands on either side of control chamber and press sides of channel together.
- Channel should be collapsed with control chamber at one end, forming a banana shape.

CAUTION

Be careful not to stretch the tubes when folding the dual-stage channel.

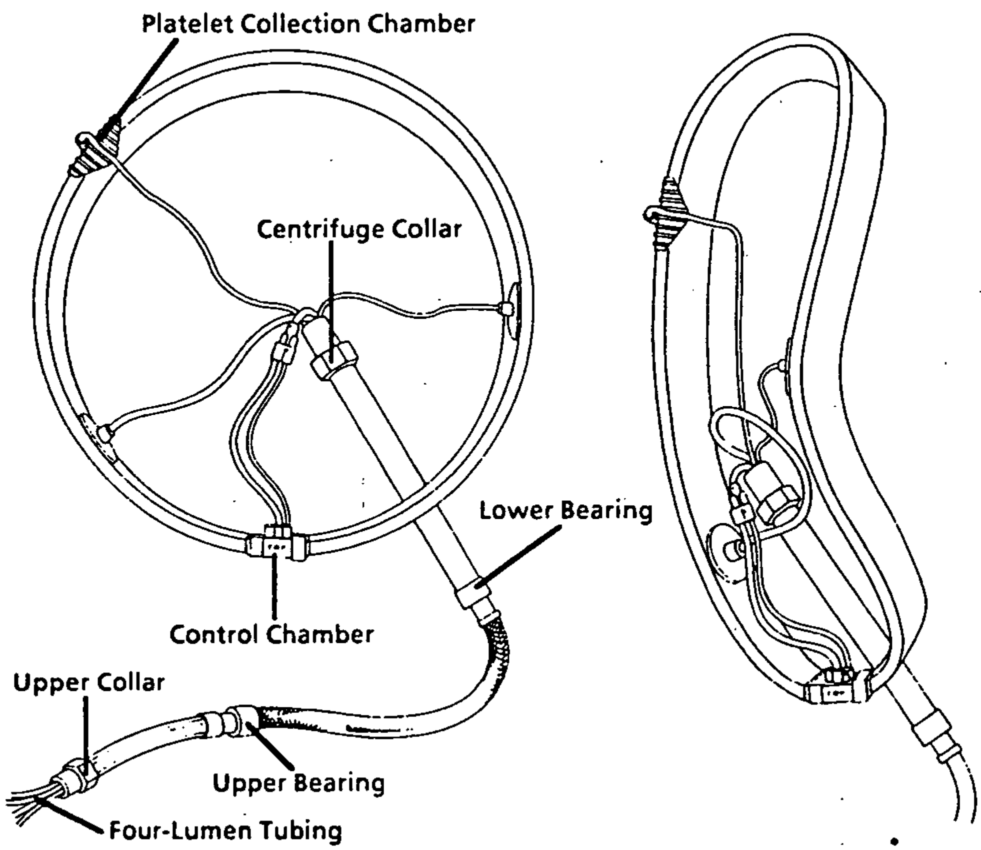

Figure 4A-3. Correctly Folded Dual-Stage Channel

Operator Action	System Action
10. Position channel in correct orientation above filler slots before placing centrifuge collar (Figure 4A-3) into centrifuge collar holder (Figure 4A-1).	
11. Thread channel through lower loading port and pull it out from the top.	
12. Load centrifuge collar into centrifuge collar holder, closing cover over collar.	
13. Lower filler latch into locked position.	
14. Press channel into position, ensuring it is completely loaded in filler. Start at control chamber and work around in both directions toward the collection chamber (Figure 4A-3).	
15. Press tubes into appropriate slots in filler, ensuring all tubes are completely inserted.	
16. Place lower bearing (Figure 4A-3) in lower bearing holder (No. 10 in Figure 1-13).	
17. Place upper bearing (Figure 4A-3) in upper bearing holder (No. 11 in Figure 1-13).	
18. Place upper collar (Figure 4A-3) in upper collar holder (No. 12 in Figure 1-13). Ensure that collar is held securely by visually checking that both black sides of holder are equally closed around collar and that an edge between two of the upper collar's six sides is facing out. Be sure that one of the upper collar's six sides is *not* facing out . See Figure 4A-4.	
19. Place four-lumen tubing in exit slot on right side of system. Ensure that the line to the Collect Concentration Monitor is not kinked or twisted.	
20. Rotate centrifuge several times to ensure tubing does not twist and upper bearing remains in place.	

WARNING

Inspect all lines, especially those in the centrifuge and on the front panel, to ensure they are not kinked. Lines that are occluded, or partially occluded, may lead to the procedure not operating correctly.

Operator Action	System Action
21. Close centrifuge door and cover.	

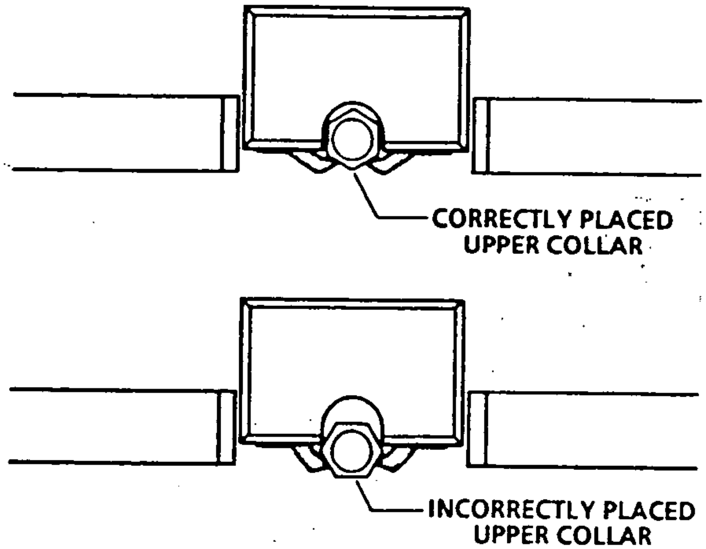

Figure 4A-4. Upper Collar Placement

Operator Action | **System Action**

Prime Tubing Set

(See Figure 1-8.)

When only single-port saline containers are available and/or hypersensitivity reactions associated with ethylene oxide sterilization must be avoided, see **HOW TO USE AN ALTERNATIVE SINGLE-PASS PRIME PROCEDURE** in SECTION 10 – HELPFUL HINTS.

> Select set: 1 = Platelets or ELP,
> 2 = TPE, 3 = WBC, 4 = RBCX

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

1. Press 1 key to select platelet tubing set.

   If you make a mistake and enter the wrong set number:

   - Press the CHANGE MODE key.
   - Press 1 key to select Load Set.
   - Press the 1 key to select the Platelets blood tubing set and continue with Step 2.

If the Single-Needle Option is installed, this message is displayed:

> Select:
> 1 = Single needle, 2 = Dual needle.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

2. Press 2 key to select Dual needle.

Operator Action	System Action
	Clamp access and return lines. Close both saline lines. Press CONTINUE.
	All Pumps -- Stopped Centrifuge -- Stopped Waste Valve -- Load Position Plasma Valve -- Load Position Collect Valve -- Load Position RBC Line Valve -- Open Return Line Valve -- Open
3. Close white pinch clamps on access and return lines near needle connections. Close roller clamps on access and return saline lines.	
4. Press CONTINUE key.	
	Connect Platelet tubing set to fluid containers. Press CONTINUE.
	All Pumps -- Stopped Centrifuge -- Stopped Waste Valve -- Load Position Plasma Valve -- Return Position Collect Valve -- Return Position RBC Line Valve -- Open Return Line Valve -- Closed

CAUTION

Use aseptic technique throughout this procedure.

5. Connect AC line to anticoagulant container, and place AC line in AC level detector.

6. Connect inlet and return saline lines to same saline container. Using aseptic technique, clean injection port before inserting metal spike into it. Then place plastic spike in spike port (after removing cover). Fill drip chambers 1/2 full.

CAUTION

Ensure lines are attached to correct fluids:

1. **AC line to anticoagulant container.**

2. **Access and return saline lines to normal saline container.**

Visually verify that fluid is flowing into the access, return, and AC drip chambers.

Operator Action	System Action

7. Press CONTINUE key.

> Open access and return saline lines.
> Press CONTINUE to prime.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

WARNING

Once fluid has entered the tubing set, do not disturb sensors in pressure sensor housings because this will prevent transducers from monitoring pressures accurately. (See SECTION 12 – RECOVERY PROCEDURES for information on how to load pressure sensors with fluid in the tubing set.)

8. Open access and return saline roller clamps.

9. Press CONTINUE key to prime tubing set.

If Spectra system was not turned off after the last procedure, it will go through a short self-check before beginning Prime.

> Power up tests in progress.

NOTE

Cuvette should not be disturbed once priming begins because the Collect Concentration Monitor is calibrated during Prime mode.

> Priming anticoagulant line.
> (Platelet Set) Prime

AC Pump	-- 100 ml/min
Inlet Pump	-- 150 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Inlet Divert Position
Plasma Valve	-- Collect Position
Collect Valve	-- Collect Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- 30 ml AC
Approximate Time	-- 18 seconds

10. Move bags to correct positions on IV pole as follows:

●	●	●	●	●
AC	Saline	Waste	Plasma	Platelet Collect

Operator Action	System Action

11. Donor data can be entered before tubing set is primed, during Prime mode, or after priming is complete:

    a. To enter donor data before Prime mode, select set type (1 = Platelets or ELP) and press MENU ON/OFF key. Continue with Step 11d.

    b. To enter donor data during Prime mode, press MENU ON/OFF key. Continue with Step 11d.

    c. To enter donor data after priming is complete, continue with Step 12.

    d. Press 1 key to select "Data Entry". (Refer to following section, **Enter Donor Data**, for instructions on how to enter donor information.)

Priming inlet line and air chamber. (Platelet Set)	Prime

AC Pump	-- Stopped
Inlet Pump	-- 100 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Inlet Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Volume	-- Fluid in Inlet Air Chamber Plus 25 ml
Approximate Time	-- 48 seconds

This step pumps saline through the access saline line, inlet line, and inlet air chamber. To prime the waste line, saline flows for a short time after fluid is detected in inlet air chamber.

Testing sensors, valves, and pumps.	Prime

AC Pump	-- Stopped
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Varies Flow Rate
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Varies Position
Return Line Valve	-- Varies Position
Approximate Time	-- 51 seconds

Operator Action

System Action

Several valves change position as the system does a series of self-checks to ensure front panel components have been loaded correctly.

Priming centrifuge channel. Prime

AC Pump	-- Stopped
Inlet Pump	-- 100 ml/min
Plasma Pump	-- 30 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 400 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 182 ml Inlet
Approximate Time	-- 110 seconds

Priming centrifuge channel. Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/min
Plasma Pump	-- 20 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 20 ml Inlet
Approximate Time	-- 10 seconds

Priming centrifuge channel. Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/ min
Plasma Pump	-- 20 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 20 ml Inlet
Approximate Time	-- 10 seconds

Operator Action	System Action

> Priming centrifuge channel.
> Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/min
Plasma Pump	-- 10 ml/min
Collect Pump	--Stopped
Centrifuge	-- 1600 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 20 ml Inlet
Approximate Time	-- 10 seconds

> Testing sensors, valves, and pumps.
> Prime

AC Pump	-- Stopped
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Stopped
Collect Pump	-- Varies Flow Rate
Centrifuge	-- 1600 rpm
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Time	-- 12 seconds

> Priming return air chamber.
> Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- 15 ml/min
Centrifuge	-- 2000 rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- Fluid in Return Air Chamber Plus 25 ml
Approximate Time	-- 48 seconds

Operator Action	System Action

Priming return lines.
Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- 2400 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 50 ml Inlet
Approximate Time	-- 25 seconds

Testing sensors, valves, and pumps.
Prime

All Pumps	-- Vary Flow Rate
Centrifuge	-- Varies
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Varies Position
RBC Line Valve	-- Varies Position
Return Line Valve	-- Varies Position
Approximate Time	-- 60 seconds

The various valves and pumps change position as the system removes air from channel and does a series of self-checks.

Prime access and return connections.
Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

12. Open white pinch clamp near access luer connection. Allow saline to fill luer lock connection by gravity. Close white pinch clamp.

13. Open white pinch clamp near return luer connection. Allow saline to fill luer lock connection by gravity. Close white pinch clamp.

14. Press CONTINUE key.

Operator Action	System Action
	Close access saline line. Clamp access line. Press CONTINUE to test AC ratio.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

15. Use roller clamp to close green-striped access saline line, close white access pinch clamp, and press CONTINUE to test the AC ratio.

> Testing AC ratio.
> Prime

AC Pump	-- Varies Flow Rate
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Time	-- 11 seconds

The AC and inlet pumps change flow rates as the Spectra system does a series of self-checks.

> WARNING: Do not connect donor/patient before running Alarm Tests. CONTINUE.

16. Press CONTINUE key to clear this warning from screen.

> Perform alarm tests (YES/NO)?

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Time	-- 9 seconds

Operator Action	System Action
17. Press YES key to run semiautomatic alarm tests. Refer to SECTION 9 – DIAGNOSTICS for **ALARM TESTS** procedure.	At this point the Spectra system provides an opportunity to verify that key alarm systems are fully operational. Alarm tests will check operation of access pressure sensor, return air detector, return pressure sensor, fluid leak detector, and centrifuge door and cover safety system.

NOTE

To clear saline from return saline drip chamber (so saline drip can be observed), do the following:

1. Clamp line below chamber.
2. Invert container and squeeze saline from drip chamber into saline container.
3. Rehang saline container.
4. Remove clamp.

18. Continue with **Enter Donor Data** steps.

Enter Donor Data

The Spectra system will customize platelet collections by using donor data to calculate pump flow rates, centrifuge speed, collect volume, inlet/anticoagulant ratio, and procedure time.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

```
Select sex:   1 = Male,  2 = Female.
   (ENTER = Male)
```


CLI 121591

Operator Action	System Action
1. Enter donor sex: • Press 1 if male. • Press 2 if female. • Press ENTER for default (data in parentheses).	(English units - enter feet): Enter height, in feet: {0} , and/or inches: 0 (Range: 1 to 7 feet)
2. Enter donor height:	

Feet and Inches	Inches	Centimeters
__ feet plus ENTER then __ inches plus ENTER	ENTER then __ inches plus ENTER	__ centimeters plus ENTER
Range: 1-7 ft	Range: 12-84 in.	Range: 30-220 cm

Operator Action	System Action
	(English units): Enter weight, in pounds: {0} (Range: 10 to 500 lbs)
3. Enter donor weight in pounds (or kilograms). Then press ENTER key.	
	Total blood volume = ________ ml. (_____ in, _____ lbs, Female). OK (YES/NO)? To confirm input, the Spectra system displays estimated total blood volume and donor data. Total blood volume is calculated from donor data entered into system. The second line of display reviews data input: height, weight, and sex.

Operator Action	System Action
4. Confirm donor data input: • Press NO one time = weight entry display. Press NO two times = height entry display. Press NO three times = sex entry display. • Press YES = next display: hematocrit entry.	
	Enter hematocrit (%): {41} (Range: 10% to 70%)
5. Enter hematocrit as a whole number. (Decimal point is not required.) Then press ENTER.	The Spectra system will use default values of 45% for males and 41% for females. **NOTE** If default values for hematocrit are used, inlet:AC ratio will be based on default value rather than on donor hematocrit and, hence, may not yield best collection performance and storage characteristics.
	Enter platelet pre-count, in cells/microliter: {250} x 1000 (Range: 1 to 2,000 = 1,000 to 2 ,000,000/ul
6. Enter donor platelet pre-count in thousands per microliter. Then press ENTER.	The Spectra system will use a default value of 250,000/ul. **NOTE** If default value for platelet pre-count is used, yield and concentration calculations will be based on default value and may not give accurate values for predicted yield and concentration.
	1 = no plasma, 2 = collect plasma. (ENTER = no plasma)
7. The Spectra system allows plasma to be concurrently collected with platelets: a. Press 1 or ENTER key if you do not want to concurrently collect plasma. b. Press 2 if you want to concurrently collect plasma.	

Operator Action | **System Action**

```
Yield = _._E11, collect = _____, conc = __,___,
plasma = ____, time = ___ min.   OK (YES/NO)?
```

The Spectra system uses donor data (entered by the operator) and microprocessor algorithms to calculate and show the following information on the platelet yield display:

- Platelet yield displayed to the eleventh power (for example, 4E11 = 4 x 10^{11}).
- Collect volume displayed in milliliters.
- Platelet concentration in collect bag displayed in thousands per microliter (x 1000). (Default value is 1,400,000 per microliter.)
- Plasma volume in milliliters.
- Procedure time displayed in minutes. (Default time is 100 minutes.)

8. Approve platelet collection values:
   - Press YES = exit donor data entry displays and continue to **Connect Donor** section.
   - Press NO = next display: *platelet settings message*.

```
Change: 1 = run time, 2 = inlet flow,
3 = collect volume, 4 = conc, 5 = plasma.
```

IMPORTANT: When one value is changed, this will affect other values. For example, increasing the inlet flow rate will increase the AC infusion rate back to the donor. (See Tables 4A-1 and 4A-2 for other examples of how changing one platelet collection value affects others.)

Table 4A-1. Effect Changing One Platelet Collection Value Has on Others When Plasma Is Not Being Collected or a Fixed Plasma Volume Has Been Entered

Changed Value	Affected Value
Run Time	Platelet Yield Inlet Volume Platelet Collect Volume AC Volume
Inlet Flow	AC Infusion Rate Platelet Yield Inlet Volume Platelet Collect Volume AC Volume
Platelet Collect Volume	Increased Volume = Lower Platelet Concentration and Slight Increase in Platelet Yield Inlet Volume AC Volume Inlet Flow Decreased Volume = Higher Platelet Concentration and Slight Decrease in Platelet Yield Inlet Volume AC Volume Inlet Flow
Platelet Collect Concentration	Increased Platelet Concentration = Lower Platelet Collect Volume and Slight Decrease in Platelet Yield Inlet Volume AC Volume Inlet Flow Decreased Platelet Concentration = Higher Platelet Collect Volume and Slight Increase in Platelet Yield Inlet Volume AC Volume Inlet Flow

Table 4A-2. Effect Changing One Platelet Collection Value Has on Others If "Collect Plasma" Is Selected in Step 7

Changed Value	Affected Value
Run Time	Platelet Yield Inlet Volume Platelet Collect Volume Plasma Volume AC Volume
Inlet Flow	AC Infusion Rate Platelet Yield Inlet Volume Platelet Collect Volume AC Volume Plasma Volume
Platelet Collect Volume	Increased Volume = Lower Platelet Concentration and Lower Plasma Volume Decreased Volume = Higher Platelet Concentration and Higher Plasma Volume
Platelet Collect Concentration	Increased Platelet Concentration = Lower Platelet Collect Volume and Higher Plasma Volume Decreased Platelet Concentration = Higher Platelet Collect Volume and Lower Plasma Volume
Plasma Volume	Once plasma volume has been changed, use Table 4A-1.

9. Select platelet collection value to be changed:

- Press 1 = braces around run time
- Press 2 = braces around inlet flow rate
- Press 3 = braces around collect volume
- Press 4 = braces around concentration
- Press 9 = redisplays *concurrent plasma collection selection message* (precedes Step 7 above)

Operator Action	System Action
	Yield = __.__E11, collect = _____, conc = __,___, plasma = ___ time = ___ min. Inlet = ___.__

10. Using arrow keys, change selected value. The up arrow key increases the value, and the down arrow key decreases it. Affected value(s) will also be changed. When satisfied that changed and affected values are appropriate, press ENTER to return to *platelet yield message* (follows Step 7 above). Press CLEAR key to return to *platelet settings message* (follows Step 8 above).

    When changing platelet and plasma collection values, the following value ranges are allowed for changed values.

Changed Value	Allowed Range
Run Time	10-999 min
Inlet Flow	15-150 ml/min
Platelet Collect Volume	10-9999 ml
Platelet Collect Concentration	100-8,000 (100,000-8,000,000/ul)
Plasma Volume	0-999 ml*

* Maximum allowable plasma volume can be increased to 1500 ml via the Total Plasma Collect Volume Entry Configuration. (See Configuration Selection Messages in Appendix A.)

11. Follow the steps below to monitor the effect that increasing the inlet flow rate has on the AC infusion rate and to verify that the AC infusion rate does not exceed the prescribed limit for the donor:

    a. Press MENU ON/OFF key.

Operator Action	System Action
b. Press 1 key to select "Data Entry."	1 = Data Entry, 2 = Pressure Display, 3 = CCM, 4 = Air Remove, 5 = Strobe, 6 = Config., 7 = SN.

Operator Action	System Action
	1 = Change procedure, 2 = Change donor information, 3 = Run results, 4 = AC data.
c. Press 4 key to display the *AC status message*.	
	AC infusion rate: 0.8 ml/min/liter TBV. ml AC in bags: collect:_____, plasma:______.
d. Press MENU ON/OFF key a second time to redisplay the *platelet yield message* (follows Step 7 above).	

Connect Donor

> **WARNING**
>
> **Before connecting donor, check access and return lines for air. If air is present in these lines, do not connect donor. Remove air before starting procedure.**

Connect access and return lines. Close access saline. Press CONTINUE to Run.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

1. Perform venipuncture at access and return needle sites.

> **WARNING**
>
> **The extended storage of platelets at 22°C requires strict awareness of any possible sources of extrinsic contamination. Rigorous attention should be paid to proper venipuncture site selection and decontamination.**

2. Open white pinch clamps on access and return lines.

Operator Action | **System Action**

3. Leave a saline drip on the return line to keep return needle from clotting.

4. Close roller clamp on access saline line.

Start Run Mode

1. Press CONTINUE key to start system in Run mode.

All pumps will start and centrifuge speed will increase based on parameters preset by donor data and Spectra algorithms.

AC	Inlet	Plasma	Collect / Replace	Inlet : AC Ratio	Spin RPM
__.__	___.__	___.__	___.__	___.__	_____

Diverting prime saline.

AC Pump	-- ___._ ml/min
Inlet Pump	-- ___._ ml/min
Plasma Pump	-- ___._ ml/min
Collect Pump	-- ___._ ml/min
Ratio	-- _ : 1
Centrifuge	-- ______ rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

NOTE

It is normal that a small amount of red cells may be diverted to the waste bag when prime saline is diverted.

2a. If you want to divert the prime saline to the waste bag, continue with Step 3.

OR

2b. If you do not want to divert the prime saline to the waste bag and, instead, want to return it to the donor, follow these steps:

- Press the CHANGE MODE key.
- Press 3 key to select Run.
- Close the roller clamp on the return saline line. (The system will not prompt you to do this.)
- Press CONTINUE key.
- Continue with Step 4, but **do not** press CLEAR.

Operator Action	System Action
	AC · Inlet · Plasma · Collect Replace · Inlet : AC Ratio · Spin RPM __.__ ___.__ ___.__ ___.__ ___.__ _____ Close return saline. Press CLEAR. AC Pump -- ___.__ ml/min Inlet Pump -- ___.__ ml/min Plasma Pump -- ___.__ ml/min Collect Pump -- ___.__ ml/min Ratio -- __ : 1 Centrifuge -- _____ rpm Waste Valve -- Closed Plasma Valve -- Variable Position Collect Valve -- Variable Position RBC Line Valve -- Open Return Line Valve -- Open Audio: Operator-attention alarm sounds.
3. Use roller clamp to close the green-striped return saline line because blood flow is being returned to donor.	
4. Press CLEAR key.	The Spectra system automatically establishes red cell/plasma interface and waits until 200 ml of inlet volume have been processed before collecting platelets that have entered second stage of dual-stage channel. If concurrent plasma collection was selected in Step 7 of the **Enter Donor Data** mode, the Spectra system will wait until at least 500 ml of inlet volume have been processed and then place the plasma valve in the collect position and begin collecting plasma, also from the second stage of the dual-stage channel. The Spectra system displays pump flow rates, anticoagulant ratio, centrifuge rpm, accumulated volumes processed by each pump, procedure time (in minutes), and procedure type.

Operator Action

NOTE

If centrifuge step down is enabled, refer to *centrifuge step down selection message* in APPENDIX A.

System Action

```
 AC      Inlet     Plasma    Collect   Inlet . AC   Spin
                             Replace     Ratio      RPM
+----------------------------------------------------------+
| _._   ___._   ___._   ___._   ___._     ____           |
| ___   _____   _____   _____   _____     PLTC           |
+----------------------------------------------------------+
                             Collect     Time     Procedure
 AC      Inlet     Plasma    Replace     Min
```

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- _______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

```
 AC      Inlet     Plasma    Collect   Inlet  AC    Spin
                             Replace     Ratio      RPM
+----------------------------------------------------------+
| _._   ___._   ___._   ___._   ___._   _____            |
| Establishing interface, Inlet = 45 ml/min.               |
+----------------------------------------------------------+
```

This screen is displayed during dual-needle Platelet procedures if all three situations below are true:

- The high flow protocol is enabled. (See *high flow selection message* in APPENDIX A.)
- The inlet flow rate is greater than 45 ml/min.
- The calculated or displayed inlet volume is less than 500 ml. During this step, the system is establishing a stable red blood cell/plasma interface. The inlet flow rate will increase after 500 ml of inlet volume have been processed.

If the above screen is displayed, the actual flow rates will be lower than those displayed in the screen.

```
 AC      Inlet     Plasma    Collect   Inlet . AC   Spin
                             Replace     Ratio      RPM
+----------------------------------------------------------+
| _._   ___._   ___._   ___._   ___._     ____           |
| ___   _____   _____   _____   _____     PLTC           |
+----------------------------------------------------------+
                             Collect     Time     Procedure
 AC      Inlet     Plasma    Replace     Min
```

Operator Action	System Action
	The previous screen will display once the interface is established.
5. If you have already entered the Run mode before you decide to concurrently collect plasma, you can do so at this point by following these steps: a. Press TARGET key to display current end-of-run target values. b. Press PLASMA VOLUME key. c. Enter volume of plasma you want to collect. d. Press TARGET key a second time to redisplay the screen immediately above with its current actual volume values.	
	Run mode continues until target values are reached. Values that have exceeded their limits will be flashing. There are audio and visual warnings when Run mode is complete.

```
End of Run:  1 = Rinseback, 2 = Continue Run.
___   _____  _____  _____  _____   PLTC
```

AC	Inlet	Plasma	Collect Replace	Time Min	Procedure

AC Pump -- ___.__ ml/min
Inlet Pump -- ___.__ ml/min
Plasma Pump -- ___.__ ml/min
Collect Pump -- ___.__ ml/min
Ratio -- __ : 1
Centrifuge -- ______ rpm
Waste Valve -- Closed
Plasma Valve -- Variable Position
Collect Valve -- Variable Position
RBC Line Valve -- Open
Return Line Valve -- Open

Operator Action	System Action
6. Press 2 key to continue Run mode. (To start Rinseback mode, press 1 key and skip to **Start Rinseback Mode** section.)	If no selection is made, a shutdown alarm will occur after 10 minutes and the pumps will stop.

Operator Action	System Action
	Increase flashing target limits. ___ ____ ____ ____ ____ Target AC Inlet Plasma Collect/Replace Time/Min Procedure AC Pump -- ___._ ml/min Inlet Pump -- ___._ ml/min Plasma Pump -- ___._ ml/min Collect Pump -- ___._ ml/min Ratio -- _ : 1 Centrifuge -- ____ rpm Waste Valve -- Closed Plasma Valve -- Variable Position Collect Valve -- Variable Position RBC Line Valve -- Open Return Line Valve -- Open
7. Select flashing target value on bottom row of display.	Inlet volume processed and time elapsed are only values that flash.
8. To increase inlet volume or time, press appropriate key.	
9. Enter new target value on numeric keypad. Then press ENTER.	Run mode continues until target values are reached. There are audio and visual warnings when Run mode is complete.
	End of Run: 1 = Rinseback, 2 = Continue Run. ___ ____ ____ ____ ____ PLTC AC Inlet Plasma Collect/Replace Time/Min Procedure AC Pump -- ___._ ml/min Inlet Pump -- ___._ ml/min Plasma Pump -- ___._ ml/min Collect Pump -- ___._ ml/min Ratio -- _ : 1 Centrifuge -- ____ rpm Waste Valve -- Closed Plasma Valve -- Variable Position Collect Valve -- Variable Position RBC Line Valve -- Open Return Line Valve -- Open

Operator Action	System Action

Start Rinseback Mode

1. Press 1 key to start Rinseback mode.

If no selection is made, a shutdown alarm will occur after 10 minutes.

> Clamp & disconnect access. Open access saline. Press CONTINUE to Rinseback.

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- _______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

2. Close white pinch clamp on access line. Open roller clamp on green-striped access saline line to allow saline to enter system.

3. Press CONTINUE key to start Rinseback.

4. Disconnect access needle and place in appropriate needle disposal container.

> Rinseback: Collecting.
> Rinse.

AC Pump	-- Stopped
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Centrifuge	-- _______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- CCM Reading of < 100,000
Appropriate Time	-- 30 seconds

The system will continue to collect platelets during first few minutes of Rinseback mode until CCM shows the concentration is too low to collect or until 50 milliliters of inlet volume have been processed.

Operator Action	System Action

Rinseback: Collecting step is skipped if collect valve is in return position. For example, during a red cell spillover, CCM moves collect valve automatically to return position.

> Clamp and disconnect collection bags.
> Press CLEAR.

AC Pump	-- Stopped
Inlet Pump	-- 50.0.ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

NOTE

If the inlet flow was higher than 50 ml/min during the Run mode, the inlet pump will run at the higher rate.

5. **IMPORTANT**: Clamp or seal collect line above and below luer connection and remove platelet product bags. If concurrent plasma has been collected, clamp or seal plasma line and remove plasma product bag.

6. Press CLEAR to continue Rinseback.

> Rinseback: Returning RBCs.
> Rinse.

AC Pump	-- Stopped
Inlet Pump	-- 50.0.ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 90 ml Inlet
Approximate Time	-- 108 seconds

Red blood cell line is only flow back to donor during this step.

Operator Action	System Action

NOTE

If the inlet flow was higher than 50 ml/min during the Run mode, the inlet pump will run at the higher rate.

Rinseback: Recirculating. Rinse.

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma Pump	-- 150.0 ml/min
Collect Pump	-- 50.0 ml/min
Centrifuge	-- Stopped
Waste Valve	-- Recirculate Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Volume	-- 225 ml Plasma
Approximate Time	-- 90 seconds

The Spectra system closes return line valve and flushes red cells off channel wall by recirculating saline through channel at high speed.

NOTE

No flow to or from donor during this step.

Rinseback: Evacuating channel. Rinse.

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma Pump	-- 50.0 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 100 ml Plasma
Approximate Time	-- 150 seconds

The Spectra system opens return line valve so free red cells can be returned to donor. Channel is collapsed to reduce extracorporeal blood volume.

Operator Action	System Action
	Rinseback: Rinsing channel.. Rinse.

AC Pump	-- Stopped
Inlet Pump	-- 50.0 ml/min
Plasma Pump	-- 50.0 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 58 ml Inlet
Approximate Time	-- 70 seconds

The Spectra system allows additional saline to enter channel to flush final red cells back to donor.

NOTE

If the inlet flow was higher than 50 ml/min during the Run mode, the inlet pump will run at the higher rate.

Disconnect Donor

NOTE

Before disconnecting donor, verify that platelet and plasma product bags are clamped or sealed and removed and that the line below the collect bag is clamped.

Rinseback completed. Disconnect return line. Close fluids. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed

1. When Rinseback mode is completed, close white pinch clamp on return line. Disconnect return needle. Close roller clamp on green-striped access saline line.

2. To ensure that fluids do not leak when disposables are removed, close slide clamps at the collect and plasma lines and, when possible, connect return line to collect line (where collect bag was disconnected).

Operator Action	System Action
3. Press CONTINUE key.	Final values. Press CONTINUE to unload. ____ ____ ____ ____ ____ ____ AC Inlet Plasma Collect/Replace Time Min Procedure All Pumps -- Stopped Centrifuge -- Stopped Waste Valve -- Load Position Plasma Valve -- Load Position Collect Valve -- Load Position RBC Line Valve -- Open Return Line Valve -- Open
4. Record on donor records final volumes processed during procedure.	

REMOVING PLATELET DISPOSABLES

Operator Action	System Action

(See Figure 1-13.)

1. Place ends of donor access and return lines in appropriate biohazard disposal container.
2. Press UNLOCK COVER key.
3. Slide centrifuge cover back.
4. Lower centrifuge door.
5. Remove four-lumen tubing from exit slot on right side of the system.
6. Remove collar from upper collar holder.
7. Remove upper bearing from upper bearing holder.
8. Remove lower bearing from lower bearing holder.
9. Push filler latching pin toward center of centrifuge and raise filler latch.
10. Pull tubes from slots in filler.
11. Pull channel from filler.
12. Open hinged cover on centrifuge collar holder and remove collar.
13. Raise channel above filler.
14. Fold channel in half and pull through loading port.
15. Discard channel in appropriate biohazard disposal container. (Channel will still be connected to tubing.)
16. Close centrifuge door and cover.

Operator Action	System Action

17. Remove lines from the following:

- Collect and plasma valves
- Return pressure sensor
- Waste divert valve
- RBC line valve
- Collect concentration monitor
- Return and inlet air detectors
- Centrifuge pressure sensor
- Access pressure sensor
- Return line valve
- Anticoagulant level detector

18. Press CONTINUE key to unload pumps.

> Unloading pumps.
> Unload

All Pumps	-- 48 ml/min
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Time	-- 7 seconds

19. Remove lines from cartridge clamps (press clamps up to release pump cartridges).

20. Remove return needle and needle in saline container from tubing set and place them in appropriate needle disposal container.

21. Remove fluid containers and waste bag from Spectra system and place in appropriate biohazard disposal container along with tubing.

> COBE Spectra (Revision __).
> Press CONTINUE to load tubing set.

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4b-Platelet SN
Operation

SECTION 4B - PLATELET SINGLE-NEEDLE OPERATION

This single-needle procedure is intended for use when a Platelet blood tubing set is used to collect donor platelets for storage up to 24 hours. Steps are included for converting the dual-needle Platelet blood tubing set to single-needle operation by addition of a single-needle bag and a "Y" connector. The "Y" connector provides for the replacement of the access and return needles with a single needle that provides both functions in a single-needle procedure. See SECTION 4A - PLATELET DUAL-NEEDLE OPERATION for Platelet dual-needle procedure.

REQUIRED EQUIPMENT AND SUPPLIES

DUAL- AND SINGLE-NEEDLE PROCEDURES

- COBE Spectra™ Apheresis System
- Dual-stage platelet channel filler
- Collect flow path overlay
- Disposable Platelet blood tubing set (Catalog Number 777004-000)
- Anticoagulant (ACD-A – each 100 ml contains: 2.2 g sodium citrate hydrous, 730 mg citric acid anhydrous, and 2.45 g dextrose hydrous)
- 0.9% sodium chloride for injection (1000 ml). When only single-port saline containers are available and/or hypersensitivity reactions associated with ethylene oxide sterilization must be avoided, see **HOW TO USE AN ALTERNATIVE SINGLE-PASS PRIME PROCEDURE** in SECTION 10 – HELPFUL HINTS.
- Forceps or hemostats

SINGLE-NEEDLE PROCEDURES ONLY

- Single-Needle Set: Single-needle bag and "Y" connector (Catalog Number 777000-100)
- Return Flow Controller (Catalog Number 951000-000)
- One needle
- Blood pressure cuff

NOTE

Using the same donor, a 10%-15% longer procedure time may be required to produce a yield of single-needle platelet product equivalent to the yield of a dual-needle platelet procedure.

NOTE

During Single-Needle Platelet collections, the COBE Spectra Apheresis System collects leukocyte-poor platelet concentrate with an average WBC content of 3.5 X 10^7 per product. The actual WBC counts may increase depending upon

- Limitations of WBC counting technique
- Spillovers during the procedure
- Concurrent plasma collection

SETTING UP EQUIPMENT

Operator Action	System Action

Check System

1. Plug in Spectra Apheresis System.
2. Turn power switch ON.

The system will go through a short self-check to ensure that the various power supplies are operating at the correct voltage.

> Power up tests in progress.

> COBE Spectra (Program Revision __).
> Press CONTINUE to load tubing set.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- *Load Position
Plasma Valve	-- *Load Position
Collect Valve	-- *Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

*Refer to Appendix A for an explanation of valve positions.

3. Verify the following:
   - Yellow warning LED is illuminated.
   - "COBE Spectra (Revision __)" is displayed.
   - PAUSE LED is flashing.
   - Cartridge clamps are in load position.
   - Single-Needle Option is installed.
     - Press MENU ON/OFF key.
     - Press 6 to select Configuration.
     - Press ENTER key twice to reach the third configuration screen.
     - Press 3 to select SN.
     - If the next screen says that the Single-Needle Option is not installed, press 1 to install it and press MENU ON/OFF key to remove message.

Operator Action	System Action
– If next screen says that the Single-Needle Option is installed, press MENU ON/OFF key to remove message.	

Install Return Flow Controller

If the Return Flow Controller is not already installed on the IV pole, install it following the instructions of the **INSTALLATION OF RETURN FLOW CONTROLLER** section of SECTION 2 – INSTALLATION.

Install Filler

1. Press UNLOCK COVER key.
2. Slide centrifuge cover back.
3. Lower centrifuge door.
4. Rotate centrifuge so centrifuge loading port (with alignment dot) is facing the front. (See Figure 4B-1.)
5. If a single-stage channel filler is in place, remove it as follows:
   - Push filler latching pin (No. 5 in Figure 1-13) toward center of centrifuge and raise filler latch (No. 6 in Figure 1-13).
   - Push filler locking pin (No. 4 in Figure 1-13) toward center of centrifuge and raise filler.
6. Position dual-stage platelet channel filler so dots on centrifuge and filler are aligned. (See Figure 4B-1.)
7. Place filler over centrifuge assembly, and press down until filler locking pin is securely in place.
8. Lower filler latch.
9. Lift up on filler to ensure it is securely in place.
10. Close centrifuge door and cover.
11. Install collect flow path overlay on front panel.

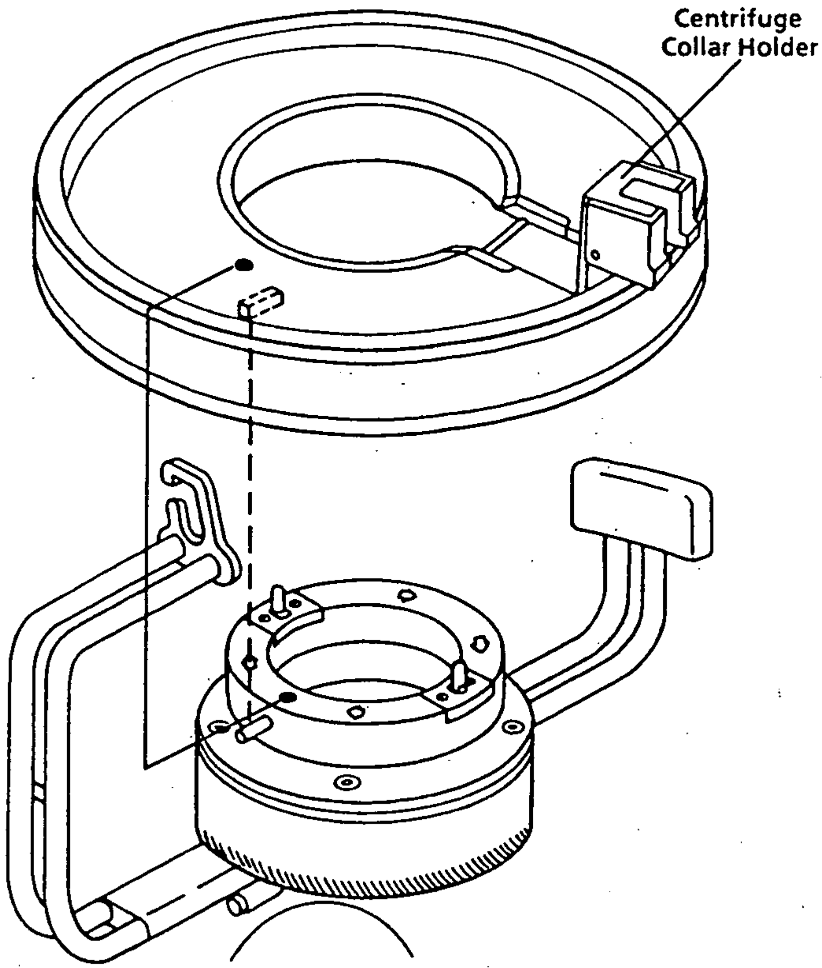

Figure 4B-1. Correct Filler/Centrifuge Alignment

Operator Action	System Action

Place Tubing on Front Panel

(See Figure 1-14.)

1. Swing control panel to the side.
2. Peel back cover on disposables package.
3. Place disposables set package on centrifuge cover.
4. Package should be held securely by placing it underneath packaging hook on front panel.
5. Remove inlet line coil and remove white paper tapes. (See Figure 4B-2.)

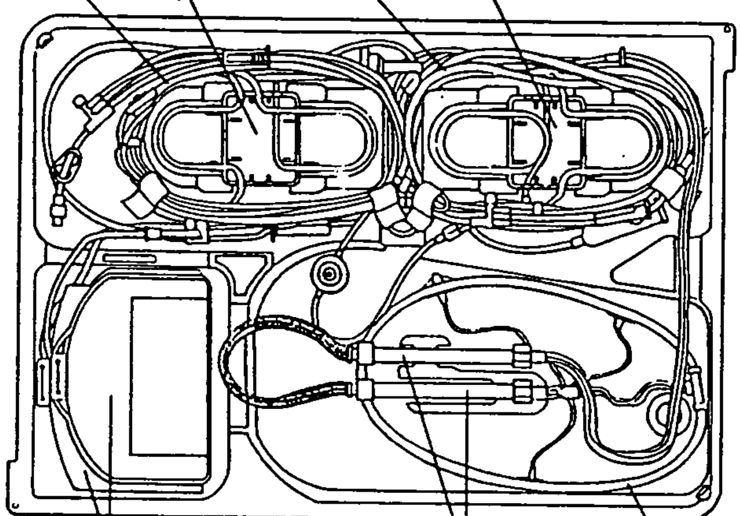

Figure 4B-2. Packaged Tubing Set

a. Hang donor/patient connection on hook on left side of IV pole. (For identification purposes, the three lines attached to this connection are taped together with red tape until they reach the front panel.)

b. Place access saline line (green striped) over the top of the system.

6. Remove return line coil and remove white paper tapes. (See Figure 4B-2.)

Operator Action	System Action
a. Hang donor/patient connection on hook on left side of IV pole. (For identification purposes, the two lines attached to this connection are taped together with blue tape until they reach the front panel.)	
b. Place return saline line over the top of the system.	
7. Using aseptic technique, connect the "Y" connector to the access and return lines and the access/return needle:	
a. Remove "Y" connector from Single-Needle Set.	
b. Remove protective cap from one female port of of the "Y" connector (Figure 1-12) and connect that port to the male port on the access line.	
c. Remove protective cap from other female port on the "Y" connector and connect that port to the male port on the return line.	
d. Remove protective cap from the male port on the "Y" connector and connect that port to the access/return needle.	
e. Secure but do not overtighten all three connections.	
8. Hang bags on one hook on the IV pole.	
9. Remove return pump cartridge and snap it into the cartridge clamp between plasma and collect/replace pump. (COBE label on cartridge should be facing up.)	
10. Remove access pump cartridge and snap it into the cartridge clamp between the AC and inlet pumps. (COBE label on cartridge should be facing up.)	
11. Place AC line over top of the system.	
12. Ensure that all tubing is clear of pumps and untangled.	

Operator Action	System Action
13. Press CONTINUE key to load tubing into pump housings.	Cartridge clamps are retracted and tubing headers are threaded onto pump rotors.

Loading pumps. Load

All Pumps	-- 48 ml/min
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Collect Position
Collect Valve	-- Collect Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Time	-- 10 seconds

14. Verify all four pumps are loaded.

After pumps are loaded, valves automatically open to load position.

15. Put lines in collect/replace and plasma valves.

16. Place sensor in return pressure sensor housing. Press down and turn clockwise to lock in place.

17. Install Collect Concentration Monitor cuvette as follows:

- Pull housing out and turn counterclockwise to lock into the Load (Open) position.
- While holding tubing on both sides of cuvette, slide cuvette into position in collect concentration monitor, being sure that a flat side of the cuvette is parallel to the front panel.

NOTE

Take care not to touch cuvette because finger prints may cause inaccurate platelet readings.

- Release housing by turning clockwise and gently lower over cuvette to lock into position.

18. Place RBC line in RBC valve. Ensure line is completely inserted in RBC detector.

19. Position return and inlet air chambers in air detectors with air chamber filters located below air detector housings. Ensure waste divert lines are toward you.

20. Put waste lines in waste valve assembly.

Operator Action	System Action
21. Place line in centrifuge pressure sensor housing. Use a "flossing" action to ensure line is completely inserted in pressure sensor.	
22. Place sensor in access pressure sensor housing. Push down and turn clockwise to lock in place.	
23. Position return line in return valve so line runs horizontally through center of valve.	
24. Release four-lumen tubing from package retainers.	

Install Single-Needle Bag

1. Place Return Flow Controller into Load position by turning its flow control handcrank (Figure 1-16) all the way counter-clockwise to the Load position. (See Figure 1-18.)

2. Remove the single-needle bag from the Single-Needle Set and load it into the space that Step 1 created at the top of the Return Flow Controller:

NOTE

The single-needle bag is symmetrical and may be loaded with either side up.

a. Hold bag in your right hand so that the end with the locator hole (Figure 1-12) is pointing toward your left.

b. Loosely fold the bag in half lengthwise to facilitate its insertion into the Return Flow Controller.

c. Insert the locator hole end of the bag into the right side of the space made at the top of the Return Flow Controller by Step 1.

d. Grasp the bag's load tab (Figure 1-12) through the Return Flow Controller's left side access port and place the bag's locator hole over the bag locator pin on the bag mounting plate. (See Figure 1-16.)

e. Ensure that the bag is lying flat on the plate.

Operator Action

System Action

f. Place the bag's tubes on either side of the bag alignment block.

3. Using aseptic technique, connect the single-needle bag to Platelet blood tubing set:

   a. Connect male luer lock (No. 29 above return air chamber in Figure 1-8) of Platelet set to female port on single-needle bag.

   b. Connect female luer lock of Platelet set to male port on single-needle bag.

   c. Secure but do not overtighten both connections.

Install Channel in Centrifuge

(See Figure 1-13.)

1. Remove channel (Figure 4B-2) from package.
2. Discard package.
3. Press UNLOCK COVER key.
4. Slide centrifuge cover back.
5. Lower centrifuge door.
6. Rotate centrifuge so loading port (No. 8 in Figure 1-13) is open to the front.
7. Ensure that centrifuge collar holder is resting on the outer rim of the filler. (See position of centrifuge collar holder in Figure 4B-1.) If centrifuge collar holder is not resting on the outer rim of the filler, push filler latching pin (No. 5 in Figure 1-13) toward center of centrifuge, raise filler latch (No. 6 in Figure 1-13), and place it on the outer rim.
8. Extend centrifuge loop to full length to ensure four-lumen tubing is not twisted.

Operator Action	System Action
9. Fold channel in half as follows (see Figure 4B-3): • Hold channel so control chamber is toward you. • Place hands on either side of control chamber and press sides of channel together. • Channel should be collapsed with control chamber at one end, forming a banana shape.	

CAUTION

Be careful not to stretch the tubes when folding the dual-stage channel.

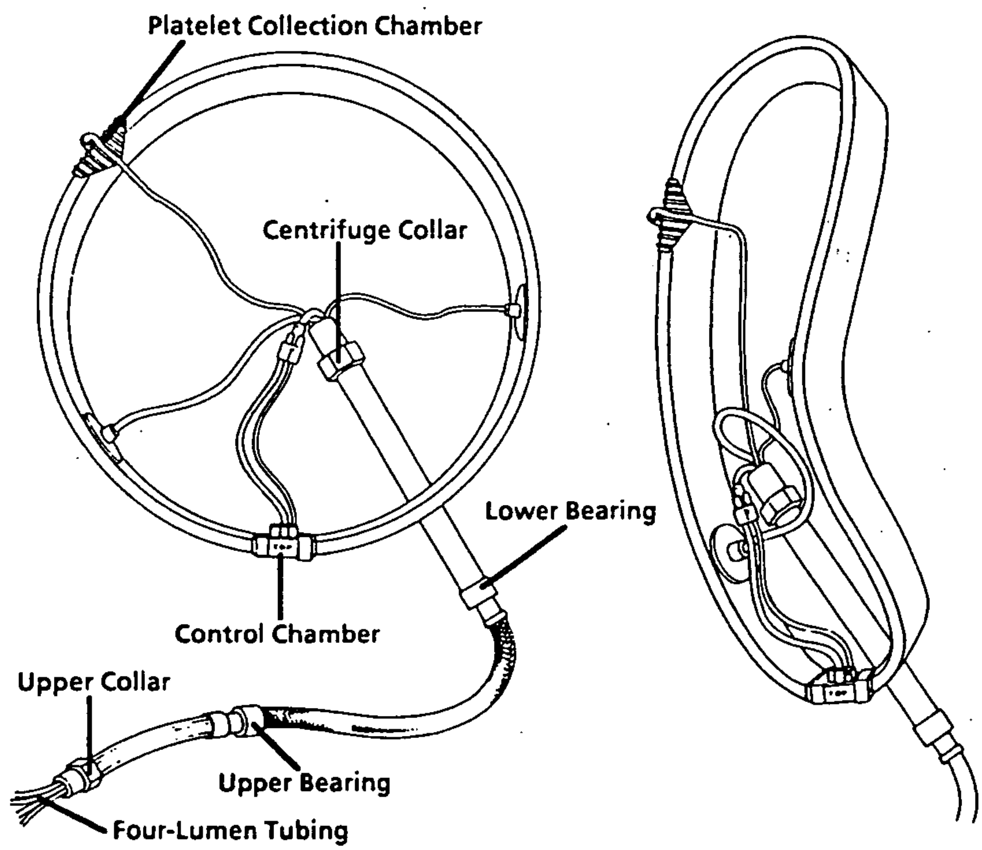

Figure 4B-3. Correctly Folded Dual-Stage Channel

Operator Action	System Action
10. Thread channel through lower loading port (No. 8 in Figure 1-13) and pull it out from the top.	
11. Position channel in correct orientation above filler slots before placing centrifuge collar (Figure 4B-3) into centrifuge collar holder (Figure 4B-1).	
12. Load centrifuge collar into centrifuge collar holder, closing cover over collar.	
13. Lower filler latch into locked position.	
14. Press channel into position, ensuring it is completely loaded in filler. Start at control chamber and work around in both directions toward the collection chamber (Figure 4B-3).	
15. Press tubes into appropriate slots in filler, ensuring all tubes are completely inserted.	
16. Place lower bearing (Figure 4B-3) in lower bearing holder (No. 10 in Figure 1-13).	
17. Place upper bearing (Figure 4B-3) in upper bearing holder (No. 11 in Figure 1-13).	
18. Place upper collar (Figure 4B-3) in upper collar holder (No. 12 in Figure 1-13). Ensure that collar is held securely by visually checking that both black sides of holder are equally closed around collar and that an edge between two of the upper collar's six sides is facing out. Be sure that one of the upper collar's six sides is *not* facing out . See Figure 4B-4.	
19. Use a "flossing" action to place four-lumen tubing in exit slot on right side of system. Ensure that the line to the Collect Concentration Monitor is not kinked or twisted.	

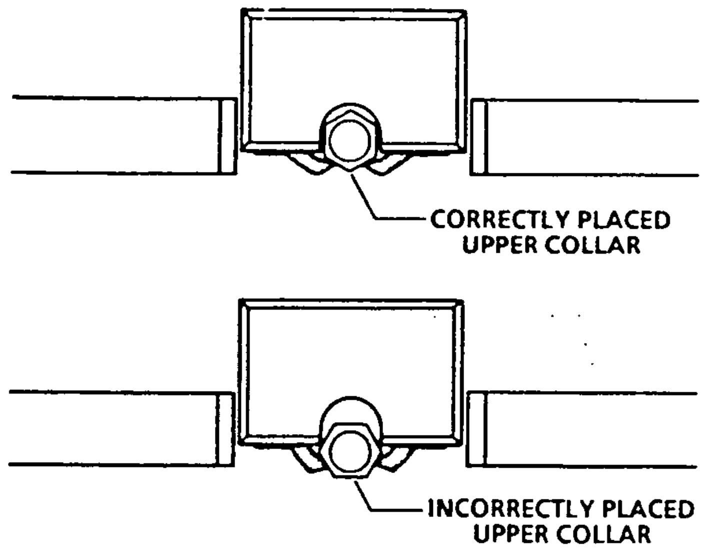

Figure 4B-4. Upper Collar Placement

Operator Action	System Action
20. Rotate centrifuge several times to ensure tubing does not twist and upper bearing remains in place.	

WARNING

Inspect all lines, especially those in the centrifuge and on the front panel, to ensure they are not kinked. Lines that are occluded, or partially occluded, may lead to the procedure not operating correctly.

21. Close centrifuge door and cover.

Operator Action	System Action

Prime Tubing Set

(See Figure 1-8.)

When only single-port saline containers are available and/or hypersensitivity reactions associated with ethylene oxide sterilization must be avoided, see **HOW TO USE AN ALTERNATIVE SINGLE-PASS PRIME PROCEDURE** in SECTION 10 – HELPFUL HINTS. The single-pass prime procedure can also be used with single-needle Platelet collection procedures.

> Select set: 1 = Platelets or ELP,
> 2 = TPE, 3 = WBC, 4 = RBCX

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

1. Press 1 key to select platelet tubing set.

   If you make a mistake and enter the wrong set number:

   - Press the CHANGE MODE key.
   - Press 1 key to select Load Set.
   - Press the 1 key to select the Platelet blood tubing set and continue with Step 2.

If the Single-Needle Option is installed, this message is displayed:

> Select:
> 1 = Single needle, 2 = Dual needle.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

2. Press 1 key to select "Single needle."

Operator Action	System Action
	When Single-Needle Option is selected in Step 2, this message is displayed.

> Set return flow scale to prime.
> Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

3. Place Return Flow Controller in Prime position by cranking its flow control handcrank (Figure 1-16) clockwise until it can no longer turn. (See "Prime Position" illustration in Figure 1-18.) Do not use excessive force when cranking the handcrank.

4. Verify that the single-needle bag is pressed flat between the plates of the Return Flow Controller and that the lines leaving the right side of the bag are not kinked or twisted.

5. Press CONTINUE key.

> Clamp needle line.
> Close saline line(s). Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

6. Close clamp on access/return needle or clamp with hemostat if no clamp is present. Close roller clamp on access saline line and roller clamp on return saline line.

7. Press CONTINUE key.

> Connect Platelet tubing set to
> fluid containers. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

Operator Action | System Action

CAUTION

Use aseptic technique throughout this procedure.

8. Connect AC line to anticoagulant container, and place AC line in AC level detector.

9. Connect inlet and return saline lines to same saline container. Using aseptic technique, clean injection port before inserting metal spike into it. Then place plastic spike in spike port (after removing cover). Fill drip chambers 1/2 full.

CAUTION

Ensure lines are attached to correct fluids:

1. AC line to anticoagulant container.

2. Access and return saline lines to normal saline container.

Visually verify that fluid is flowing into the access, return, and AC drip chambers.

10. Press CONTINUE key.

Open saline line(s).
Press CONTINUE to prime.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

WARNING

Once fluid has entered the tubing set, do not disturb sensors in pressure sensor housings because this will prevent transducers from monitoring pressures accurately. (See SECTION 12 - RECOVERY PROCEDURES for information on how to load pressure sensors with fluid in the tubing set.)

11. Open access and return saline roller clamps.

Operator Action	System Action
12. Press CONTINUE key to prime tubing set.	If Spectra system was not turned off after the last procedure, it will go through a short self-check before beginning Prime.

> Power up tests in progress.

NOTE

Cuvette should not be disturbed once priming begins because the Collect Concentration Monitor is calibrated during Prime mode.

> Priming anticoagulant line.
> (Platelet Set) Prime

AC Pump	-- 100 ml/min
Inlet Pump	-- 150 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Inlet Divert Position
Plasma Valve	-- Collect Position
Collect Valve	-- Collect Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- 30 ml AC
Approximate Time	-- 18 seconds

13. Move bags to correct positions* on IV pole as follows:

●	●	●	●	●	●
AC	Saline	Waste	Single Needle**	Plasma	Platelet Collect

* Some bags, for example, the AC and saline bags, will need to share the front and back of the same hook.

** Installed in Return Flow Controller

14. Donor data can be entered before tubing set is primed, during Prime mode, or after priming is complete:

a. To enter donor data before Prime mode, select set type (1 = Platelets or ELP) and press MENU ON/OFF key. Continue with Step 14d.

b. To enter donor data during Prime mode, press MENU ON/OFF key. Continue with Step 14d.

c. To enter donor data after priming is complete, continue with Step 15.

d. Press 1 key to select "Data Entry". (Refer to following section, **Enter Donor Data**, for instructions on how to enter donor information.)

Operator Action	System Action

Priming inlet line and air chamber. (Platelet Set)	Prime

AC Pump	-- Stopped
Inlet Pump	-- 100 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Inlet Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Volume	-- Fluid in Inlet Air Chamber Plus 40 ml
Approximate Time	-- 57 seconds

This step pumps saline through the access saline line, inlet line, and inlet air chamber. To prime the waste line, saline flows for a short time after fluid is detected in inlet air chamber.

Testing sensors, valves, and pumps.	Prime

AC Pump	-- Stopped
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Varies Flow Rate
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Varies Position
Return Line Valve	-- Closed
Approximate Time	-- 51 seconds

Several valves change position as the system does a series of self-checks to ensure front panel components have been loaded correctly.

Priming centrifuge channel.	Prime

AC Pump	-- Stopped
Inlet Pump	-- 100 ml/min
Plasma Pump	-- 30 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 400 rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- 182 ml Inlet
Approximate Time	-- 110 seconds

Operator Action	System Action

Priming centrifuge channel. Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/min
Plasma Pump	-- 20 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- 20 ml Inlet
Approximate Time	-- 10 seconds

Priming centrifuge channel. Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/ min
Plasma Pump	-- 20 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- 20 ml Inlet
Approximate Time	-- 10 seconds

Priming centrifuge channel. Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/min
Plasma Pump	-- 10 ml/min
Collect Pump	--Stopped
Centrifuge	-- 1600 rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- 20 ml Inlet
Approximate Time	-- 10 seconds

Operator Action	System Action

Testing sensors, valves, and pumps.
Prime

AC Pump	-- Stopped
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Stopped
Collect Pump	-- Varies Flow Rate
Centrifuge	-- 1600 rpm
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Time	-- 12 seconds

Priming return air chamber.
Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- 15 ml/min
Centrifuge	-- 2000 rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- Fluid in Return Air Chamber Plus 25 ml
Approximate Time	-- 48 seconds

Priming return lines.
Prime

AC Pump	-- 10 ml/min
Inlet Pump	-- 120 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- 2400 rpm
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Varies Position
Approximate Volume	-- 50 ml Inlet
Approximate Time	-- 25 seconds

The air in the return line is pumped through the return saline line into the saline bag.

Operator Action	System Action

Testing sensors, valves, and pumps.
Prime

All Pumps	-- Vary Flow Rate
Centrifuge	-- Varies
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Varies Position
RBC Line Valve	-- Varies Position
Return Line Valve	-- Varies Position
Approximate Time	-- 60 seconds

The various valves and pumps change position as the system removes air from channel and does a series of self-checks.

Priming single needle bag.
Prime

All Pumps	-- Vary Flow Rate
Centrifuge	-- Varies
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Varies Position
Return Line Valve	-- Varies Position

Prime donor connection.
Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

15. Unclamp the needle and allow saline to fill needle by gravity.

16. Close needle pinch clamp or clamp needle with hemostat if no clamp is present.

Operator Action	System Action
17. Press CONTINUE key.	

> Close access saline line. Clamp access line. Press CONTINUE to test AC ratio.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Inlet Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

18. Use roller clamp to close green-striped access saline line, close white access pinch clamp, and press CONTINUE to test the AC ratio.

> Testing AC ratio.
> Prime

AC Pump	-- Varies Flow Rate
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Inlet Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Time	-- 11 seconds

The AC and inlet pumps change flow rates as the system does a series of self-checks.

> WARNING: Do not connect donor/patient before running Alarm Tests. CONTINUE.

19. Press CONTINUE key to clear this warning from screen.

Operator Action	System Action
	Perform alarm tests (YES/NO)?

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Time	-- 9 seconds

20. Press YES key to run semiautomatic alarm tests. Refer to SECTION 9 – DIAGNOSTICS for **ALARM TESTS** procedure.

At this point the Spectra system provides an opportunity to verify that key alarm systems are fully operational. Alarm tests will check operation of access pressure sensor, return air detector, return pressure sensor, fluid leak detector, and centrifuge door and cover safety system.

NOTE

To clear saline from return saline drip chamber (so saline drip can be observed), do the following:

1. Clamp line below chamber.
2. Invert container and squeeze saline from drip chamber into saline container.
3. Rehang saline container.
4. Remove clamp.

21. Continue with **Enter Donor Data** steps.

Enter Donor Data

The Spectra system will customize platelet collections by using donor data to calculate pump flow rates, centrifuge speed, collect volume, inlet/anticoagulant ratio, and procedure time.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Operator Action	System Action

Select sex: 1 = Male, 2 = Female.
(ENTER = Male)

1. Enter donor sex:

- Press 1 if male.
- Press 2 if female.
- Press ENTER for default (data in parentheses).

(English units - enter feet):

Enter height,
in feet: {0} , and/or inches: 0

(Range: 1 to 7 feet)

2. Enter donor height:

Feet and Inches	Inches	Centimeters
__ feet plus ENTER then __ inches plus ENTER	ENTER then __ inches plus ENTER	__ centimeters plus ENTER
Range: 1-7 ft	Range: 12-84 in.	Range: 30-220 cm

(English units):

Enter weight,
in pounds: {0}

(Range: 10 to 500 lbs)

3. Enter donor weight in pounds (or kilograms).
Then press ENTER key.

Total blood volume = ________ ml.
(_____ in, _____ lbs, Female). OK (YES/NO)?

To confirm input, the Spectra system displays estimated total blood volume and donor data. Total blood volume is calculated from donor data entered into system. The second line of display reviews data input: height, weight, and sex.

Operator Action	System Action
4. Confirm donor data input: • Press NO one time = weight entry display. Press NO two times = height entry display. Press NO three times = sex entry display. • Press YES = next display: hematocrit entry.	
	Enter hematocrit (%): {41} (Range: 10% to 70%)
5. Enter hematocrit as a whole number. (Decimal point is not required.) Then press ENTER.	The Spectra system will use default values of 45% for males and 41% for females. **NOTE** If default values for hematocrit are used, inlet:AC ratio will be based on default value rather than on donor hematocrit and, hence, may not yield best collection performance.
	Enter platelet pre-count, in cells/microliter: {250} x 1000 (Range: 1 to 2,000 = 1,000 to 2 ,000,000/ul
6. Enter donor platelet pre-count in thousands per microliter. Then press ENTER.	The Spectra system will use a default value of 250,000/ul. **NOTE** If default value for platelet pre-count is used, yield and concentration calculations will be based on default value and may not give accurate values for predicted yield and concentration.
	1 = no plasma, 2 = collect plasma. (ENTER = no plasma)
7. The Spectra system allows plasma to be concurrently collected with platelets: a. Press 1 or ENTER key if you do not want to concurrently collect plasma. b. Press 2 if you want to concurrently collect plasma.	

Operator Action	System Action
	Yield = _._E11, collect = _____, conc = __,____, plasma = ____, time = ___ min. OK (YES/NO)?
	The Spectra system uses donor data (entered by the operator) and microprocessor algorithms to calculate and show the following information on the platelet yield display: • Platelet yield displayed to the eleventh power (for example, 4E11 = 4 x 10^{11}). • Collect volume displayed in milliliters. • Platelet concentration in collect bag displayed in thousands per microliter (x 1000). (Default value is 1,400,000 per microliter.) • Plasma volume in milliliters. • Procedure time displayed in minutes. (Default time is 100 minutes.)
8. Approve platelet collection values: • Press YES = exit donor data entry displays and continue to **Connect Donor** section. • Press NO = next display: *platelet settings message*.	
	Change: 1 = run time, 2 = inlet flow, 3 = collect volume, 4 = conc, 5 = plasma.
IMPORTANT: When one value is changed, this will affect other values. For example, increasing the inlet flow rate will increase the AC infusion rate back to the donor. (See Tables 4B-1 and 4B-2 for other examples of how changing one platelet collection value affects others.)	

Table 4B-1. Effect Changing One Platelet Collection Value Has on Others When Plasma Is Not Being Collected or a Fixed Plasma Volume Has Been Entered

Changed Value	Affected Value
Run Time	Platelet Yield Inlet Volume Platelet Collect Volume AC Volume
Inlet Flow	AC Infusion Rate Platelet Yield Inlet Volume Platelet Collect Volume AC Volume
Platelet Collect Volume	Increased Volume = Lower Platelet Concentration and Slight Increase in Platelet Yield Inlet Volume AC Volume Inlet Flow Decreased Volume = Higher Platelet Concentration and Slight Decrease in Platelet Yield Inlet Volume AC Volume Inlet Flow
Platelet Collect Concentration	Increased Platelet Concentration = Lower Platelet Collect Volume and Slight Decrease in Platelet Yield Inlet Volume AC Volume Inlet Flow Decreased Platelet Concentration = Higher Platelet Collect Volume and Slight Increase in Platelet Yield Inlet Volume AC Volume Inlet Flow

Table 4B-2. Effect Changing One Platelet Collection Value Has on Others If "Collect Plasma" Is Selected in Step 7

Changed Value	Affected Value
Run Time	Platelet Yield Inlet Volume Platelet Collect Volume Plasma Volume AC Volume
Inlet Flow	AC Infusion Rate Platelet Yield Inlet Volume Platelet Collect Volume AC Volume Plasma Volume
Platelet Collect Volume	Increased Volume = Lower Platelet Concentration and Lower Plasma Volume Decreased Volume = Higher Platelet Concentration and Higher Plasma Volume
Platelet Collect Concentration	Increased Platelet Concentration = Lower Platelet Collect Volume and Higher Plasma Volume Decreased Platelet Concentration = Higher Platelet Collect Volume and Lower Plasma Volume
Plasma Volume	Once plasma volume has been changed, use Table 4B-1.

9. Select platelet collection value to be changed:

- Press 1 = braces around run time
- Press 2 = braces around inlet flow rate
- Press 3 = braces around collect volume
- Press 4 = braces around concentration
- Press 9 = redisplays *concurrent plasma collection selection message* (precedes Step 7 above)

Operator Action	System Action
	Yield = __.__ E11, collect = _____, conc = __,___, plasma = ___ time = ___ min. Inlet = ___.__

10. Using arrow keys, change selected value. The up arrow key increases the value, and the down arrow key decreases it. Affected value(s) will also be changed. When satisfied that changed and affected values are appropriate, press ENTER to return to *platelet yield message* (follows Step 7 above). Press CLEAR key to return to *platelet settings message* (follows Step 8 above).

    When changing platelet and plasma collection values, the following value ranges are allowed for changed values.

Changed Value	Allowed Range
Run Time	10-999 min
Inlet Flow	15-50 ml/min
Platelet Collect Volume	10-9999 ml
Platelet Collect Concentration	100-8,000 (100,000-8,000,000/ul)
Plasma Volume	0-999 ml*

* Maximum allowable plasma volume can be increased to 1500 ml via the Total Plasma Collect Volume Entry Configuration. (See Configuration Selection Messages in Appendix A.)

11. Follow the steps below to monitor the effect that increasing the inlet flow rate has on the AC infusion rate and to verify that the AC infusion rate does not exceed the prescribed limit for the donor:

    a. Press MENU ON/OFF key.

1 = Data Entry, 2 = Pressure Display, 3 = CCM, 4 = Air Remove, 5 = Strobe, 6 = Config., 7 = SN.

    b. Press 1 key to select "Data Entry."

Operator Action	System Action
	1 = Change procedure, 2 = Change donor information, 3 = Run results, 4 = AC data.
c. Press 4 key to display the *AC status message*.	
	AC infusion rate: 0.8 ml/min/liter TBV. ml AC in bags: collect:_____, plasma:_______.
d. Press MENU ON/OFF key a second time to redisplay the *platelet yield message* (follows Step 7 above).	

Connect Donor

WARNING

Before connecting donor, check access and return lines for air. If air is present in these lines, do not connect donor. Remove air before starting procedure.

Close saline line(s).
Connect donor. Press CONTINUE to Run.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

1. Close roller clamps on access and return saline lines. Close white pinch clamps on access and return lines.

2. Perform venipuncture at needle site.

WARNING

The extended storage of platelets at 22°C requires strict awareness of any possible sources of extrinsic contamination. Rigorous attention should be paid to proper venipuncture site selection and decontamination.

Operator Action	System Action
3. Open white pinch clamps on access and return lines.	
4. To improve antecubital access flow, maintain a cuff pressure of between 10 and 20 mmHg on the access/return arm.	

Start Run Mode

1. Press CONTINUE key to start system in Run mode.

All pumps will start and centrifuge speed will increase based on parameters preset by donor data and Spectra algorithms.

AC	Inlet	Plasma	Collect / Replace	Inlet : AC Ratio	Spin RPM
__.__	___.__	___.__	___.__	___.__	_____

Diverting prime saline.

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- ______ rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

NOTE

It is normal that a small amount of red cells may be diverted to the waste bag when prime saline is diverted.

2a. If you want to divert the prime saline to the waste bag, continue with Step 3.

OR

2b. If you do not want to divert the prime saline to the waste bag and, instead, want to return it to the donor, follow these steps:

- Press the CHANGE MODE key.
- Press 3 key to select Run.
- Press CONTINUE key.
- Continue with Step 3.

Operator Action	System Action
	Set return flow scale to ____. Press CONTINUE.

AC Pump	-- ____._ ml/min
Inlet Pump	-- ____._ ml/min
Plasma Pump	-- ____._ ml/min
Collect Pump	-- ____._ ml/min
Ratio	-- _ : 1
Centrifuge	-- _______ rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

Audio : Operator-attention alarm sounds.

All pump speeds, the centrifuge speed, and plasma and collect valve positions are set by alogrithms.

3. Note the number on the screen above. Turn flow control handcrank on Return Flow Controller (Figure 1-16) counterclockwise until the return flow indicator points to that number on the return flow scale (Figure 1-18).

4. Press CONTINUE key.

When the single-needle return phase is reached, the Return Flow Controller will apply the appropriate pressure to the single-needle bag to return the blood components withdrawn during the single-needle draw phase back to the donor at the correct flow rate.

The Spectra system automatically establishes red cell/plasma interface and waits until 200 ml of inlet volume have been processed before collecting platelets that have entered second stage of dual-stage channel.

If concurrent plasma collection was selected in Step 7 of the **Enter Donor Data** mode, the Spectra system will wait until at least 500 ml of inlet volume have been processed and then place the plasma valve in the collect position and begin collecting plasma, also from the second stage of the dual-stage channel.

Operator Action

System Action

During single-needle procedures, if you or the Spectra control program command the plasma or collect valve to move, this movement will not take place until the latter portion of each return phase when the return pressure is low. If you set a target volume of plasma, the single-needle procedure will proceed as follows:

- Return plasma (saline) will be returned to the donor until the inlet volume exceeds 500 ml.
- At the end of the next single-needle return phase (or at the end of the next return cycle after selecting a target volume of plasma to be collected), the Spectra control program will switch the plasma valve to the collect position.
- When the volume of plasma collected equals or exceeds the target volume, the Spectra control program will switch the plasma valve back to the return position at the end of the next single-needle return phase.
- For single-needle Platelet procedures, the Spectra control program limits the average inlet flow rate to 50 ml/min and the instantaneous inlet flow rate to 150 ml/min.

The Spectra system displays pump flow rates, anticoagulant ratio, centrifuge rpm, accumulated volumes processed by each pump, procedure time (in minutes), and procedure type. For single-needle procedures, average flow rates are displayed. Step 6 below explains how to display instantaneous single-needle flow rates.

Operator Action	System Action

System Action

AC	Inlet	Plasma	Collect Replace	Inlet : AC Ratio	Spin RPM
_._	___._	___._	___._	___._	______
___	___	___	___	___	SNPLTC
AC	Inlet	Plasma	Collect Replace	Time Min	Procedure

AC Pump	-- ___._ ml/min
Inlet Pump	-- ___._ ml/min
Plasma Pump	-- ___._ ml/min
Collect Pump	-- ___._ ml/min
Ratio	-- _ : 1
Centrifuge	-- ______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

NOTE

If centrifuge step down is enabled, refer to *centrifuge step down selection message* in APPENDIX A.

During a draw phase of a single-needle platelet collect procedure, a "D" will appear in the upper left-hand corner of the display screen. During a return phase, an "R" will appear.

5. To monitor instantaneous draw phase flow rates:

   a. Press MENU ON/OFF key.

   > 1 = Data Entry, 2 = Pressure Display, 3 = CCM,
   > 4 = Air Remove, 5 = Strobe, 6 = Config., 7 = SN.

   b. Press 7 key to select "SN" and display the *single-needle instantaneous screen.*

   c. Press MENU ON/OFF key to leave the single-needle instantaneous screen and redisplay the Spectra *SNPLTC procedure screen* above.

6. If you have already entered the Run mode before you decide to concurrently collect plasma, you can do so at this point by following these steps:

   a. Press TARGET key to display current end-of-run target values.

   b. Press PLASMA VOLUME key.

Operator Action | **System Action**

c. Enter volume of plasma you want to collect.

d. Press TARGET key a second time to redisplay the screen immediately above with its current actual volume values.

Run mode continues until target values are reached. Values that have exceeded their limits will be flashing. There are audio and visual warnings when Run mode is complete.

```
End of Run:  1 = Rinseback, 2 = Continue Run.
____  ____  ____  ____  ____           SNPLTC
                              Collect  Time  Procedure
 AC    Inlet    Plasma        Replace  Min
```

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- _______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

7. Press 2 key to continue Run mode. (To start Rinseback mode, press 1 key and skip to **Start Rinseback Mode** section.)

If no selection is made, a shutdown alarm will after 10 minutes and the pumps will stop.

```
Increase flashing target limits.
____  ____  ____  ____  ____           Target
                              Collect  Time  Procedure
 AC    Inlet    Plasma        Replace  Min
```

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- _______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

8. Select flashing target value on bottom row of display.

Inlet volume processed and time elapsed are only values that flash.

9. To increase inlet volume or time, press appropriate key.

Operator Action	System Action
10. Enter new target value on numeric keypad. Then press ENTER.	Run mode continues until target values are reached. There are audio and visual warnings when Run mode is complete.

```
End of Run:  1 = Rinseback, 2 = Continue Run.
                                       SNPLTC
____   ____   ____   ____   ____
```

AC	Inlet	Plasma	Collect Replace	Time Min	Procedure

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- _______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Start Rinseback Mode

1. Press 1 key to start Rinseback mode.

If no selection is made, a shutdown alarm will occur after 10 minutes.

```
Clamp access.  Open access saline.
Press CONTINUE to Rinseback.
```

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- _______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

2. Close white pinch clamp on the access line below the "Y" connector. Open roller clamp on green-striped access saline line to allow saline to enter the system.

3. Press CONTINUE key to start Rinseback and continue with Step 4.

5-Platelet Depletion Operation

SECTION 5 - PLATELET DEPLETION OPERATION

This procedure is intended for use when a Platelet blood tubing set or an Extended Life Platelet blood tubing set is used to deplete platelets from a patient.

NOTE

Apparent red cell spillover may occur with this procedure. The cause is not clear, but may be due to abnormal patient red cell size or density. To alleviate the problem, a) reduce the inlet flow rate to increase the centrifugal force acting on the red cells, b) reduce the plasma flow rate by increasing the patient hematocrit, or c) choose a return needle with a shorter length or 16-17 gauge to allow the free flow of red cells from the channel and return line through the return needle. Platelet depletion operations should only be conducted as dual-needle procedures. Single-needle procedures should not be used.

REQUIRED EQUIPMENT AND SUPPLIES

- COBE Spectra™ Apheresis System
- Dual–stage platelet channel filler
- Collect flow path overlay
- Disposable Platelet blood tubing set (Catalog Number 777004-000) or dual-needle ELP™ blood tubing set (Catalog Number 777003-000)
- Anticoagulant (ACD-A – each 100 ml contains: 2.2 g sodium citrate hydrous, 730 mg citric acid anhydrous, and 2.45 g dextrose hydrous)
- 0.9% sodium chloride for injection (1000 ml)
- Two needles for Platelet blood tubing set or one additional return needle for ELP set, which comes with a preattached access needle
- Forceps or hemostats

REFERENCED PROCEDURES

Refer to SECTION 4A – PLATELET DUAL-NEEDLE OPERATION or SECTION 3A – ELP DUAL NEEDLE OPERATION for the following dual-needle procedures:

- Setting up equipment
- Setting up Platelet or ELP disposables
- Priming tubing set
- Starting Rinseback mode
- Disconnecting patient
- Removing Platelet or ELP disposables

Refer to SECTION 9 – DIAGNOSTICS for the following procedure:

- Initiating alarm tests

Operator Action	System Action

Ent r Patient Data

The Spectra system will customize platelet depletions by using patient data to calculate pump flow rates, centrifuge speed, collect volume, and procedure time. The default inlet:AC ratio for platelet depletion procedures is 6:1.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Select sex: 1 = Male, 2 = Female.
(ENTER = Male)

1. Enter patient sex:
   - Press 1 if male.
   - Press 2 if female.
   - Press ENTER for default (data in parentheses).

(English units - enter feet):

Enter height,
in feet: {0} ., and/or inches: 0

(Range: 1 to 7 feet)

2. Enter patient height:

Feet and Inches	Inches	Centimeters
_ feet plus ENTER then _ inches plus ENTER	ENTER then _ inches plus ENTER	_ centimeters plus ENTER
Range: 1-7 ft	Range: 12-84 in.	Range: 30-220 cm

Operator Action	System Action
	(English units):
	Enter weight, in pounds: {0}
	(Range: 10 to 500 lbs)
3. Enter patient weight in pounds (or kilograms). Then press ENTER.	
	Total blood volume = ________ ml. (_____ in, _____ lbs, Female). OK (YES/NO)?
	To confirm input, the system displays estimated total blood volume and patient data. Total blood volume is calculated from patient data entered into system. The second line of display reviews data input: height, weight, and sex.
4. Confirm patient data input: • Press NO one time = weight entry display. Press NO two times = height entry display. Press NO three times = sex entry display. • Press YES = next display: hematocrit entry.	
	Enter hematocrit (%): {41}
	(Range: 10% to 70%)
5. Enter hematocrit as a whole number. (Decimal point is not required.) Then press ENTER.	The Spectra system will use default values of 45% for males and 41% for females.
	Enter platelet pre-count, in cells/microliter: {250} x 1000
	(Range: 1 to 2,000 = 1,000 to 2,000,000/ul)
6. Enter patient platelet pre-count in thousands per microliter. Then press ENTER.	The Spectra system will use a default value of 250,000/ul. **To select a platelet depletion procedure, enter a value greater than 400,000/ul.** • The system uses patient platelet pre-count (entered by operator) and microprocessor algorithms to calculate collect pump flow rate. • Entering a platelet pre-count of less than 1,000,000/ul will maintain the collect pump flow rate at 2 ml/min.

Operator Action	System Action
	Select procedure: 1 = Donor Collect, 2 = Patient Deplete. (ENTER = Collect)
7. Press 2 key to select patient depletion. Then press ENTER.	
	Inlet volume = _____ ml, inlet flow = ___._ time = ___ min. collect ______. OK (YES/NO)?
	The Spectra system uses patient data (entered by the operator) and microprocessor algorithms to calculate and show the following information on the platelet depletion results display: • Inlet volume displayed in milliliters • Inlet flow rate displayed in milliliters per minute • Time displayed in minutes • Collect volume displayed in milliliters
8. Approve platelet depletion values: • Press YES = exit patient data entry displays and continue to **Connect Patient** section • Press NO = next display: *platelet depletion settingsmessage*	
	Change: 1 = run time, 2 = inlet flow, 3 = collect volume, 4 = precount.
IMPORTANT: Changing one value affects other values as follows:	

Changed Value	Affected Value
Run Time	Inlet Volume Collect Volume AC Volume
Inlet Flow	Inlet Volume AC Volume AC Flow Rate
Collect Volume	Collect Flow Rate Inlet Flow Rate Inlet Volume AC Flow Rate AC Volume Plasma Pump Rate
Platelet Pre-count If >1,000,000/ul	Collect Volume

Operator Action	System Action
9. Select platelet depletion value to be changed: • Press 1 = braces around run time • Press 2 = braces around inlet flow rate • Press 3 = braces around collect volume • Press 4 = braces around platelet pre-count	Inlet volume = _____ml, inlet flow = ____.__ time = ___min. collect_______.
10. Using arrow keys, change selected value. The up arrow key increases the value, and the down arrow key decreases it. Affected value(s) on entry display will also change. When changed and affected values are appropriate, press ENTER to return to *platelet depletion results message* (follows Step 7).	

Operator Action	System Action

When changing platelet depletion values, the following value ranges are allowed for changed values:

Changed Value	Allowed Range
Run Time	10-999 min
Inlet Flow	15-150 ml/min
Platelet Collect Volume	10-9999 ml

Connect Patient

WARNING

Before connecting patient, check access and return lines for air. If air is present in these lines, do not connect patient. Remove air before starting procedure.

1. Perform venipuncture at access and return needle sites.
2. Open white pinch clamp on access and return lines.
3. Leave a saline drip on the return line to keep return needle from clotting.
4. Close roller clamp on green-striped access saline line.

Connect access and return lines. Close access saline. Press CONTINUE to Run.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

Operator Action	System Action

Start Run Mode

NOTE

During a platelet depletion procedure, the following warning alarms will not be activated: "Spillover detected, "Post-count in donor may be less than 100,000 platelets/ul," and "Total plasma collected (collect and plasma bags) exceeds ___ ml." In addition, during platelet depletion procedures, the CCM is not accurate.

1. Press CONTINUE key to start system in Run mode.

All pumps will start and centrifuge speed will increase based on parameters preset by patient data and Spectra algorithms.

AC	Inlet	Plasma	Collect Replace	Inlet:AC Ratio	Spin RPM
_._	___._	___._	___._	6.0	2400

Diverting prime saline. . .

AC Pump	-- ___._ ml/min
Inlet Pump	-- ___._ ml/min
Plasma Pump	-- ___._ ml/min
Collect Pump	-- ___._ ml/min
Ratio	-- 6 : 1
Centrifuge	-- 2400 rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

NOTE

It is normal that a small amount of red cells may be diverted to the waste bag when prime saline is diverted.

2a. If you want to divert the prime saline to the waste bag, continue with Step 3.

OR

2b. If you do not want to divert the prime saline to the waste bag and, instead, want to return it to the donor, follow these steps:

- Press the CHANGE MODE key.
- Press 3 key to select Run.
- Close the roller clamp on the return saline line. (The system will not prompt you to do this.)
- Press CONTINUE key.

Operator Action	System Action

- Continue with Step 4, but do not press CLEAR.

AC	Inlet	Plasma	Collect/Replace	Inlet : AC Ratio	Spin RPM
__.__	___.__	___.__	___.__	6.0	2400

Close return saline Press CLEAR.

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- 6 : 1
Centrifuge	-- 2400 rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Audio: Operator-attention alarm sounds.

3. Use roller clamp to close return saline line because blood flow is being returned to the patient.

4. Press CLEAR key.

The Spectra system automatically establishes red cell/plasma interface after 200 ml of blood have been processed.

The system displays pump flow rates, anticoagulant ratio, centrifuge rpm, accumulated volumes processed by each pump, procedure time (in minutes), and procedure type.

As the following formula shows, the collect pump flow rate, as calculated by the Spectra control program, is 2 ml/min or greater:

$$\frac{\text{Platelet Pre-Count}}{5 \times 10^5} = \text{Collect Flow Rate} \geq 2 \text{ ml/min}$$

Operator Action	System Action

System Action

AC	Inlet	Plasma	Collect / Replace	Inlet : AC Ratio	Spin RPM
__.__	___.__	___.__	___.__	6.0	2400
___	____	____	____	____	PLTD
AC	Inlet	Plasma	Collect / Replace	Time Min	Procedure

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- 6 : 1
Centrifuge	-- 2400 rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

5. Observe platelet collect line. If platelet clumps are seen, increase collect pump flow rate by 1 ml. Continue to monitor line, and increase pump flow rate if clumping is still apparent.

When collect pump flow rate is increased, the Spectra control program decreases plasma pump flow rate by same amount.

Run mode continues until target values are reached. There are audio and visual warnings when Run mode is complete. Values that have exceeded their limits will be flashing.

End of Run: 1 = Rinseback, 2 = Continue Run.					
___	____	____	____	____	PLTD
AC	Inlet	Plasma	Collect / Replace	Time Min	Procedure

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- _ : 1
Centrifuge	-- ______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

6. Press 2 key to continue Run mode. (To start Rinseback mode, press 1 key and skip to **Start Rinseback Mode** procedure in SECTION 4A – PLATELET DUAL-NEEDLE OPERATION or SECTION 3A – ELP DUAL-NEEDLE OPERATION.)

If no selection is made, a shutdown alarm will occur after 10 minutes and pumps will stop.

Operator Action	System Action

Increase flashing target limits.
___ _____ _____ _____ _____ Target

AC	Inlet	Plasma	Collect / Replace	Time Min	Procedure

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- _ : 1
Centrifuge	-- _______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

7. Select flashing target value on bottom row of display.

Inlet volume processed and time elapsed are only values that flash.

8. To increase inlet volume or time, press appropriate key.

9. Enter new target value on numeric keypad. Then press ENTER.

Run mode continues until target values are reached. There are audio and visual warnings when Run mode is complete.

End of Run: 1 = Rinseback, 2 = Continue Run.
___ _____ _____ _____ _____ PLTD

AC	Inlet	Plasma	Collect / Replace	Time Min	Procedure

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- _ : 1
Centrifuge	-- _______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

6a-TPE Operation

SECTION 6A - TPE DUAL-NEEDLE OPERATION

This dual-needle procedure is intended for use when a TPE blood tubing set is used to remove plasma from a patient requiring therapeutic plasma exchange. See SECTION 6B – TPE SINGLE-NEEDLE OPERATION for TPE single-needle procedure.

REQUIRED EQUIPMENT AND SUPPLIES

DUAL- AND SINGLE-NEEDLE PROCEDURES

- COBE Spectra™ Apheresis System
- Single-stage channel filler
- TPE flow path overlay
- Disposable TPE blood tubing set (Catalog Number 777005-000)
- Anticoagulant (ACD-A – each 100 ml contains: 2.2 g sodium citrate hydrous, 730 mg citric acid anhydrous, and 2.45 g dextrose hydrous). If clinical requirements make it necessary to use heparin rather than ACD-A as the anticoagulant for TPE procedures, see **HOW TO USE HEPARIN AS TPE ANTICOAGULANT** in SECTION 10 – HELPFUL HINTS.
- 0.9% sodium chloride for injection (1000 ml). When only single-port saline containers are available and/or hypersensitivity reactions associated with ethylene oxide sterilization must be avoided, see **HOW TO USE AN ALTERNATIVE SINGLE-PASS PRIME PROCEDURE** in SECTION 10 – HELPFUL HINTS.
- Replacement fluids prescribed by physician.
- Microaggregate filters for selected replacement fluids
- Forceps or hemostats

DUAL-NEEDLE PROCEDURES ONLY

- Two needles

Operator Action	System Action

Check Syst m

1. Plug in Spectra Apheresis System.

2. Turn power switch ON.

The system will go through a short self-check to ensure that the various power supplies are operating at the correct voltage.

Power up tests in progress.

COBE Spectra (Program Revision _). Press CONTINUE to load tubing set.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- *Load Position
Plasma Valve	-- *Load Position
Collect Valve	-- *Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

*Refer to Appendix A for an explanation of valve positions.

3. Verify the following:

   - Yellow warning LED is illuminated.
   - "COBE Spectra (Revision _)" is displayed.
   - PAUSE LED is flashing.
   - Cartridge clamps are in load position.

Install Filler

1. Press UNLOCK COVER key.

2. Slide centrifuge cover back.

3. Lower centrifuge door.

4. Rotate centrifuge so centrifuge loading port (with alignment dot) is facing the front. (See Figure 6A-1.)

5. If a dual-stage channel filler is in place, remove it as follows:

   - Push filler latching pin (No. 5 in Figure 1-13) toward center of centrifuge and raise filler latch (No. 6 in Figure 1-13).

Operator Action | **System Action**

- Push filler locking pin (No. 4 in Figure 1-13) toward center of centrifuge and raise filler.

6. Position single-stage channel filler so dots on centrifuge and filler are aligned. (See Figure 6A-1.)

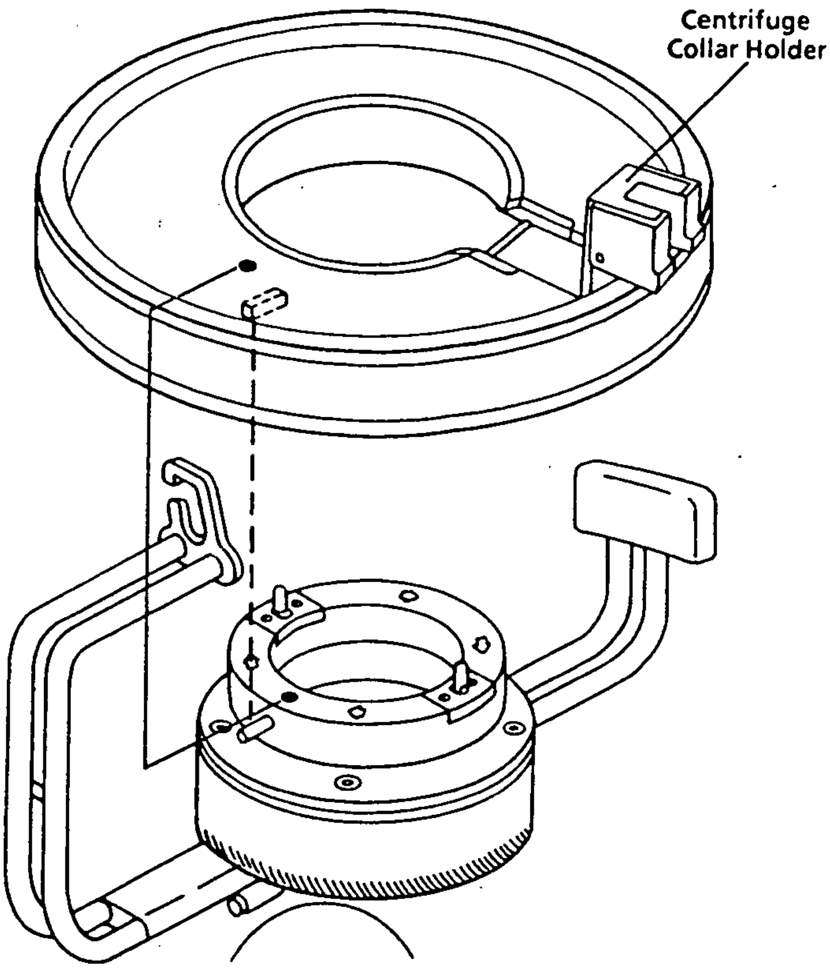

Figure 6A-1. Correct Filler/Centrifuge Alignment

7. Place filler over centrifuge assembly, and press down until filler locking pin is securely in place.

Operator Action	System Action
8. Lower filler latch.	
9. Lift up on filler to ensure it is securely in place.	
10. Close centrifuge door and cover.	
11. Install TPE flow path overlay on front panel.	

SETTING UP TPE DISPOSABLES

Operator Action | **System Action**

Place Tubing on Front Panel

(See Figure 1-14.)

1. Swing control panel to the side.
2. Peel back cover on disposables package.
3. Place disposables set package on centrifuge cover.
4. Package should be held securely by placing it underneath packaging hook on front panel.
5. Remove inlet line coil and remove white paper tapes. (See Figure 6A-2.)

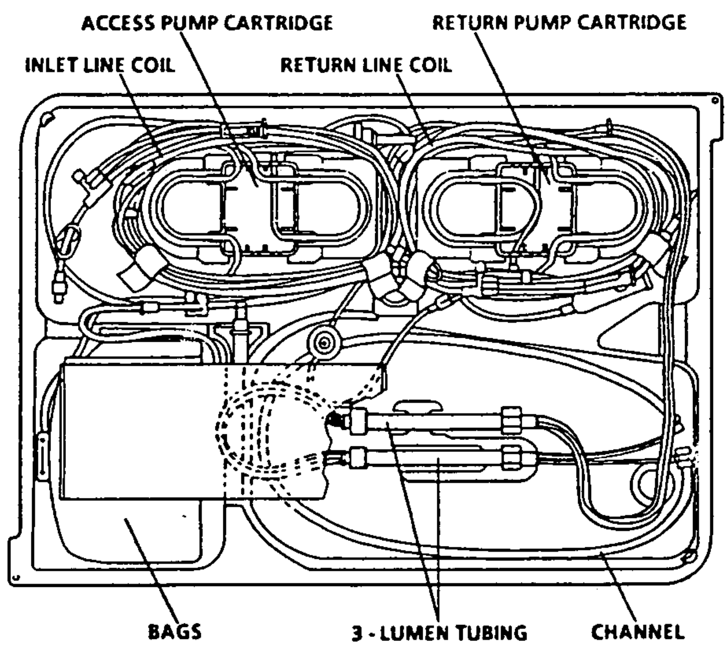

Figure 6A-2. Packaged Tubing Set

a. Hang patient connection on hook on left side of IV pole. (For identification purposes, the three lines attached to this connection are taped together with red tape until they reach the front panel.)

b. Place access saline line (green striped) over the top of the system.

Operator Action	System Action
6. Remove return line coil and remove white paper tapes. (See Figure 6A-2.) a. Hang patient connection on hook on left side of IV pole. (For identification purposes, the two lines attached to this connection are taped together with blue tape until they reach the front panel.) b. Place return saline line over the top of the system.	
7. Hang 4-liter plasma waste bag on two side-by-side hooks on IV pole (to far right). Hang prime-solution waste bag on center hook.	
8. Clamp accessory "Y" line on plasma line (right line in No. 15 in Figure 1-9).	
9. Remove return pump cartridge and snap it into the cartridge clamp between plasma and collect/replace pump. (COBE label on cartridge should be facing up.)	
10. Remove access pump cartridge and snap it into the cartridge clamp between the AC and inlet pumps. (COBE label on cartridge should be facing up.)	
11. Place AC line over top of the system.	
12. Ensure that all tubing is clear of pumps and untangled.	
13. Press CONTINUE key to load tubing into pump housings.	Cartridge clamps are retracted and tubing headers are threaded onto pump rotors. Loading pumps. Load All Pumps -- 48 ml/min Centrifuge -- Stopped Waste Valve -- Closed Plasma Valve -- Collect Position Collect Valve -- Collect Position RBC Line Valve -- Closed Return Line Valve -- Closed Approximate Time -- 10 seconds
14. Verify all four pumps are loaded.	After pumps are loaded, valves automatically open to load position.

Operator Action	System Action
15. Put lines in collect/replace and plasma valves.	
16. Lay replace solution spike assemblies over top of the system.	
17. Place sensor in return pressure sensor housing. Turn clockwise to lock in place.	
18. Place RBC line in RBC valve. Ensure line is completely inserted in RBC detector.	
19. Position return and inlet air chambers in air detectors with air chamber filters located below air detector housings. Ensure waste divert lines are toward you.	
20. Put waste lines in waste valve assembly.	
21. Place line in centrifuge pressure sensor housing. Use a "flossing" action to ensure line is completely inserted in pressure sensor.	
22. Place sensor in access pressure sensor housing. Push down and turn clockwise to lock in place.	
23. Position return line in return valve so line runs horizontally through center of valve.	
24. Using aseptic technique, connect male/female luer lock (No. 29 above return air chamber in Figure 1-9). **Secure but do not overtighten connection.**	
25. Release three-lumen tubing from package retainers.	

Install Channel in Centrifuge

(See Figure 1-13.)

1. Remove channel (Figure 6A-2) from package.
2. Discard package.
3. Press UNLOCK COVER key.
4. Slide centrifuge cover back.
5. Lower centrifuge door.

Operator Action	System Action
6. Rotate centrifuge so loading port (No. 8 in Figure 1-13) is open to the front.	
7. Ensure that centrifuge collar holder is resting on the outer rim of the filler. (See position of centrifuge collar holder in Figure 6A-1.) If centrifuge collar holder is not resting on the outer rim of the filler, push filler latching pin (No. 5 in Figure 1-13) toward center of centrifuge, raise filler latch (No. 6 in Figure 1-13), and place it on the outer rim.	
8. Extend centrifuge loop to full length to ensure three-lumen tubing is not twisted.	
9. Fold channel in half.	
10. Thread channel through lower loading port and pull it out from the top.	
11. Position channel in correct orientation above filler slots before placing centrifuge collar (Figure 6A-3) into centrifuge collar holder (Figure 6A-1).	

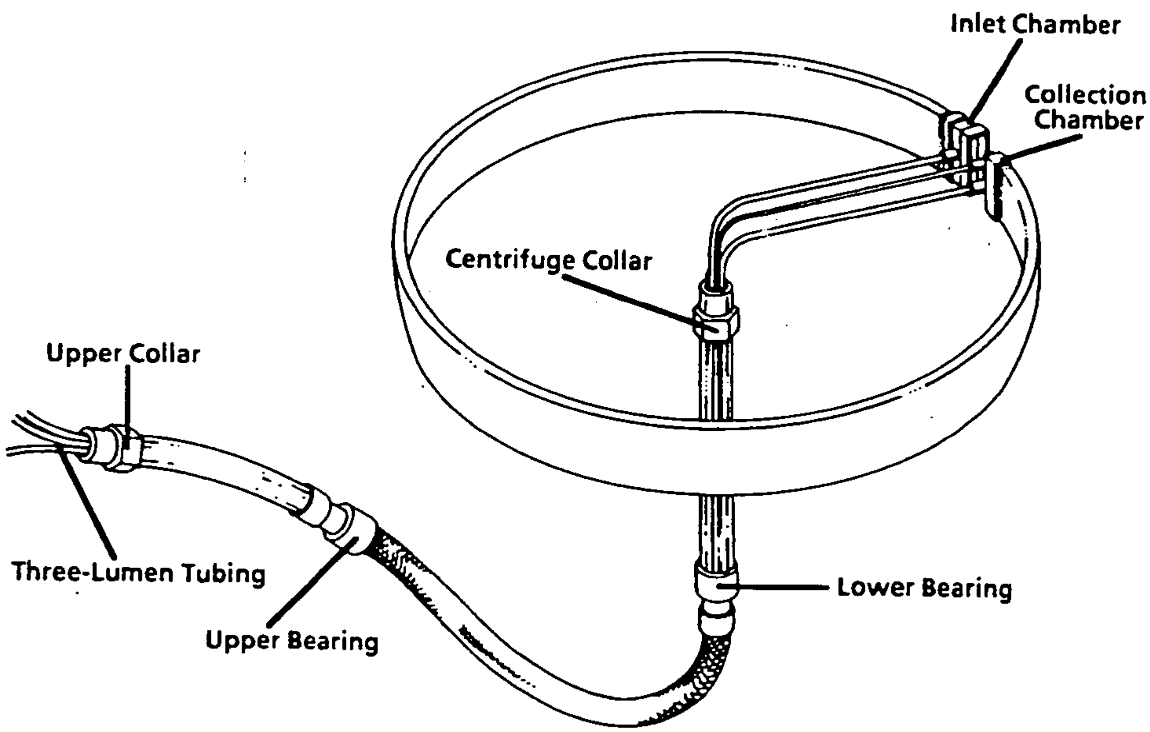

Figure 6A-3. TPE Single-Stage Channel

Operator Action | **System Action**

12. Load centrifuge collar into centrifuge collar holder, closing cover over collar.

13. Lower filler latch into locked position.

14. Press channel into position, ensuring it is completely loaded in filler. Start at collection chamber and work around toward inlet chamber (Figure 6A-3).

15. Press tubes into appropriate slots in filler, ensuring all tubes are completely inserted.

16. Place lower bearing (Figure 6A-3) in lower bearing holder (No. 10 in Figure 1-13).

17. Place upper bearing (Figure 6A-3) in upper bearing holder (No. 11 in Figure 1-13).

18. Place upper collar (Figure 6A-3) in upper collar holder (No. 12 in Figure 1-13). Ensure that collar is held securely by visually checking that both black sides of holder are equally closed around collar and that an edge between two of the upper collar's six sides is facing out. Be sure that one of the upper collar's six sides is *not* facing out. See Figure 6A-4.

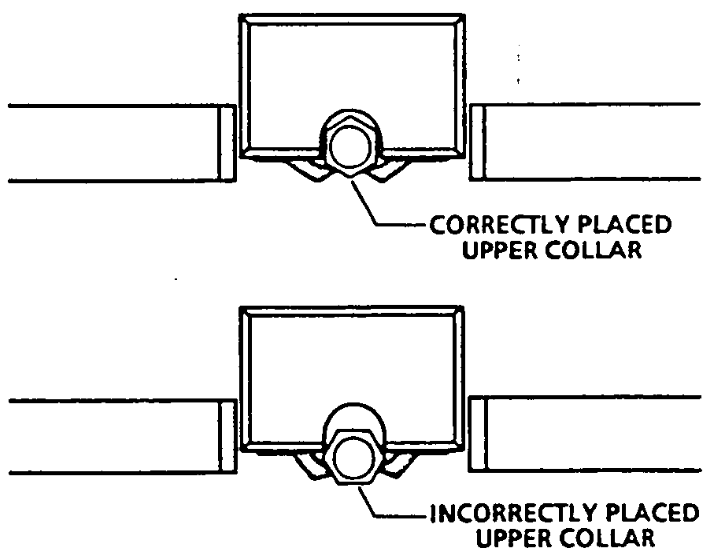

Figure 6A-4. Upper Collar Placement

Operator Action	System Action
19. Use a "flossing" action to place three-lumen tubing in exit slot on right side of the system.	
20. Rotate centrifuge several times to ensure tubing does not twist and upper bearing remains in place.	

WARNING

Inspect all lines, especially those in the centrifuge and on the front panel, to ensure they are not kinked. Lines that are occluded, or partially occluded, may lead to fluid imbalance.

21. Close centrifuge door and cover.

Operator Action	System Action

Prime Tubing Set

(See Figure 1-9.)

When only single-port saline containers are available and/or hypersensitivity reactions associated with ethylene oxide sterilization must be avoided, see **HOW TO USE AN ALTERNATIVE SINGLE-PASS PRIME PROCEDURE** in SECTION 10 - HELPFUL HINTS.

> Select set: 1 = Platelets or ELP,
> 2 = TPE, 3 = WBC, 4 = RBCX.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

1. Press 2 key to select TPE tubing set.

   If you make a mistake and enter the wrong set number:

   - Press the CHANGE MODE key.
   - Press 1 key to select Load Set.
   - Press the 2 key to select the TPE blood tubing set and continue with Step 2.

If the Single-Needle Option is installed, this message is displayed:

> Select:
> 1 = Single needle, 2 = Dual needle.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Operator Action	System Action

2. Press 2 key to select "Dual needle" if Single-Needle Option is installed.

> Clamp access and return lines.
> Close both saline lines. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

3. Close white pinch clamps on access and return lines near luer connections. Close roller clamps on access and return saline lines.

4. Press CONTINUE key.

> Connect TPE tubing set to AC, saline, &
> replacement containers. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

CAUTION

Use aseptic technique throughout this procedure.

5. Connect AC line to anticoagulant container, and place AC line in AC level detector.

NOTE

If clinical requirements make it necessary to use heparin rather than ACD-A as the anticoagulant for TPE procedures, see **HOW TO USE HEPARIN AS TPE ANTICOAGULANT** in SECTION 10 – HELPFUL HINTS.

6. Connect inlet and return saline lines to same saline container. Using aseptic technique, clean injection port before inserting metal spike into it. Then place plastic spike in spike port (after removing cover). Fill drip chambers 1/2 full.

Operator Action | System Action

CAUTION

Ensure lines are attached to correct fluids:

1. AC line to anticoagulant container.

2. Access and return saline lines to normal saline container.

Visually verify that fluid is flowing into the access, return, and AC drip chambers.

7. Connect replace solution spikes to replacement fluids prescribed by physician. (Microaggregate filters may be used for selected replacement fluids; for example, fresh frozen p..sma. Ensure filters are primed before use if required by manufacturer's instructions.) Fill drip chambers 1/2 full.

WARNING

Fluid imbalances can be caused by the following:

1. Using inadequately primed or clotted microaggregate filters used on replacement line.

2. Administering replacement fluids that are not at room temperature.

3. Using improperly vented replacement fluid containers.

4. Equipment malfunction.

5. Improper line clamping.

Monitor all solutions and procedures for correct fluid balance..

Operator Action	System Action

WARNING

The addition of calcium gluconate or other calcium salts to fresh frozen plasma may cause clotting in the replacement fluid.

Blood components containing formed elements are not recommended as replacement fluids for therapeutic plasma exchange procedures.

8. Press CONTINUE key.

Open access and return saline lines.
Press CONTINUE to prime.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

WARNING

Once fluid has entered the tubing set, do not disturb sensors in pressure sensor housings because this will prevent transducers from monitoring pressures accurately. (See SECTION 12 - RECOVERY PROCEDURES for information on how to load pressure sensors with fluid in the tubing set.)

9. Open access and return saline roller clamps.

10. Press CONTINUE key to prime tubing set.

If the Spectra system was not turned off after the last procedure, it will go through a short self-check before beginning Prime.

Power up tests in progress.

CLI 121674

Operator Action	System Action

Priming anticoagulant line.
(TPE Set) Prime

AC Pump	-- 100 ml/min
Inlet Pump	-- Stopped
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Inlet Divert Position
Plasma Valve	-- Collect Position
Collect Valve	-- Collect Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- 30 ml AC
Approximate Time	-- 18 seconds

11. Patient data can be entered before tubing set is primed, during Prime mode, or after priming is complete.

    a. To enter patient data before Prime mode, select set type (2 = TPE) and press MENU ON/OFF key. Continue with Step 11d.
    b. To enter patient data during Prime mode, press MENU ON/OFF key. Continue with Step 11d.
    c. To enter patient data after priming is complete, continue with Step 12.
    d. Press 1 key to select "Data Entry." (Refer to following section, **Enter Patient Data**, for instructions on how to enter patient information.)

Priming inlet line and air chamber.
(TPE Set) Prime

AC Pump	-- Stopped
Inlet Pump	-- 150 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Inlet Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Volume	-- Fluid in Inlet Air Chamber Plus 25 ml
Approximate Time	-- 48 seconds

This step pumps saline through the access saline line, inlet line, and inlet air chamber. To prime the waste line, saline flows for a short time after fluid is detected in the inlet air chamber.

Testing sensors, valves, and pumps.
Prime

AC Pump	-- Stopped
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Varies Flow Rate
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Varies Position
Approximate Time	-- 51 seconds

Operator Action	System Action
	Several valves change position as the system does a series of self-checks to ensure front panel components have been loaded correctly.

Priming centrifuge channel.
Prime

AC Pump	-- Stopped
Inlet Pump	-- 150 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 100 ml Inlet
Approximate Time	-- 40 seconds

Priming centrifuge channel.
Prime

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma Pump	-- 150 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 250 ml Plasma
Approximate Time	-- 100 seconds

Priming centrifuge channel.
Prime

AC Pump	-- Stopped
Inlet Pump	-- 120 ml/min
Plasma Pump	-- 120 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 82 ml Inlet
Approximate Time	-- 41 seconds

Operator Action	System Action

Priming centrifuge channel. Prime

AC Pump	-- Stopped
Inlet Pump	-- 120 ml/min
Plasma Pump	-- 120 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 200 ml Inlet
Approximate Time	-- 100 seconds

Testing sensors, valves, and pumps. Prime

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma Pump	-- Stopped
Collect Pump	-- Varies Flow Rate
Centrifuge	-- 1200 rpm
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Time	-- 12 seconds

Priming return air chamber. Prime

AC Pump	-- 12.5 ml/min
Inlet Pump	-- 150 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- 30 ml/min
Centrifuge	-- 800 rpm
Waste Valve	-- Return Divert Position.
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- Fluid in Return Air Chamber Plus 25 ml
Approximate Time	-- 48 seconds

Operator Action	System Action

System Action

> Priming return lines.
> Prime

AC Pump	-- 12.5 ml/min
Inlet Pump	-- 150 ml/min
Plasma Pump	-- 100 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 50 ml Inlet
Approximate Time	-- 20 seconds

> Testing sensors, valves, and pumps.
> Prime

AC Pump	-- Varies Flow Rate
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Varies Flow Rate
Collect Pump	-- Varies Flow Rate
Centrifuge	-- Varies
Waste Valve	-- Varies Position
Plasma Valve	-- Varies Position
Collect Valve	-- Varies Position
RBC Line Valve	-- Varies Position
Return Line Valve	--Varies Position
Approximate Time	-- 70 seconds

The various valves and pumps change position as the system removes air from the channel and does a series of self-checks.

> Prime access and return connections.
> Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Operator Action

12. Open white pinch clamp near access luer connection. Allow saline to fill luer lock connection by gravity. Close white pinch clamp.

13. Open white pinch clamp near return luer connection. Allow saline to fill luer lock connection by gravity. Close white pinch clamp.

Operator Action	System Action
14. Press CONTINUE key.	

> Close access saline line. Clamp access line. Press CONTINUE to test AC ratio.

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

15. Use roller clamp to close green-striped access saline line, close white access pinch clamp, and press CONTINUE to test the AC ratio.

> Testing AC ratio.
> Prime

AC Pump	-- Varies Flow Rate
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Time	-- 11 seconds

The AC and inlet pumps change flow rates as the system does a series of self-checks.

> WARNING: Do not connect donor/patient before running Alarm Tests. CONTINUE.

16. Press CONTINUE key to clear this warning from screen.

Operator Action	System Action
	Perform alarm tests (YES/NO)?

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Time	-- 9 seconds

17. Press YES key to run semiautomatic alarm tests. Refer to SECTION 9 – DIAGNOSTICS for **ALARM TESTS** procedure.

At this point the Spectra system provides an opportunity to verify that key alarm systems are fully operational. Alarm tests will check operation of access pressure sensor, return air detector, return pressure sensor, fluid leak detector, and centrifuge door and cover safety system.

NOTE

To clear saline from return saline drip chamber (so saline drip can be observed), do the following:

1. Clamp line below chamber.
2. Invert container and squeeze saline from drip chamber into saline container.
3. Rehang saline container.
4. Remove clamp.

18. Continue with **Enter Patient Data** steps.

Enter Patient Data

The Spectra system will customize therapeutic plasma exchange procedures by using patient data to calculate pump flow rates, centrifuge speed, remove/replace volumes, and procedure time. All therapeutic plasma exchange procedures have a default inlet:AC ratio of 10:1.

Operator Action | **System Action**

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

```
Select sex:    1 = Male,  2 =  Female.
    (ENTER = Male)
```

1. Enter patient sex:
   - Press 1 if male.
   - Press 2 if female.
   - Press ENTER for default (data in parentheses).

(English units - enter feet):

```
Enter height,
in feet:     {0}    , and/or inches:    0
```

(Range: 1 to 7 feet)

2. Enter patient height:

Feet and Inches	Inches	Centimeters
__ feet plus ENTER then __ inches plus ENTER	ENTER then __ inches plus ENTER	__ centimeters plus ENTER
Range: 1-7 ft	Range: 12-84 in.	Range: 30-220 cm

(English units):

```
Enter weight,
in pounds:   {0}
```

(Range: 10 to 500 lbs)

3. Enter patient weight in pounds (or kilograms). Then press ENTER.

```
Total blood volume  =  ________ ml.
(_____ in, _____ lbs, Female).  OK (YES/NO)?
```

Operator Action	System Action
	To confirm input, the Spectra system displays estimated total blood volume and patient data. Total blood volume is calculated from patient data entered into system. The second line of display reviews data input: height, weight, and sex.
4. Confirm patient data input: • Press NO one time = weight entry display. Press NO two times = height entry display. Press NO three times = sex entry display. • Press YES = next display: hematocrit entry.	
	Enter hematocrit (%): {41} (Range: 10% to 70%)
5. Enter hematocrit as a whole number. (Decimal point is not required.) Then press ENTER.	The Spectra system will use default values of 45% for males and 41% for females.
	Replacement fluid: 1 = Albumin/Saline, 2 = Plasma. (ENTER = Albumin/Saline)
6. Enter type of replacement fluid to be used:	The Spectra control program adjusts AC and inlet pump flow rates based on type of replacement fluid chosen. These flows are designed to minimize citrate reactions in patients.
• Press 1 if albumin/saline	Albumin/saline replacement fluid. If calcium supplements are added to replacement fluids, higher inlet flow rates may be possible. For this selection, the AC infusion rate starts at 0.6 ml/min/liter of TBV.
• Press 2 if plasma	Plasma replacement fluid derived from human plasma requires a slower infusion rate due to anticoagulant found in the fluid and potential allergic reactions at rapid infusion rates. For this selection the AC infusion rate starts at 0.8 ml/min/liter of TBV. When a new inlet flow rate is selected, the AC infusion rate will change to adjust to that inlet flow rate.

Operator Action	System Action

NOTE

If you change replacement fluid during the Run Mode, you may select the replacement fluid selection message again and change the replacement fluid selection. The Spectra system will automatically adjust the flow rates and procedure end points to reflect this change.

- Press ENTER for default (data in parentheses), which is initially albumin/saline.

Enter fluid balance desired: {100}%

(Range: 75% to 150%)

7. Either press ENTER to accept the default value of 100%, or use the arrow keys to change to a value between 75% and 150% and then press ENTER.

The system defines TPE fluid balance as combined infusion rates (replace flow plus AC flow) divided by plasma pump flow rate and multiplied by 100 as follows:

$$\textit{Percentage} = \frac{\textit{Replace Rate} + \textit{AC Rate}}{\textit{Plasma Pump Flow Rate}} \times 100$$

The system's calculation of fluid balance does not include approximately 150 ml of volume removed from patient during waste divert and approximately 345 ml of saline returned to patient during rinseback. Therefore, at 100% fluid balance, Spectra will leave patient volume expanded by 195 ml of saline.

The system calculates fluid balance not plasma balance. For a plasma balance, the amount of anticoagulant removed with plasma needs to be subtracted from the removed volume. See Step 11 for information on how to calculate the percent of anticoagulant in the plasma bag, and Step 12 for information on how to access the screen that displays the amount of anticoagulant currently in the plasma bag at any point during the procedure.

Replace = _____ ml, removed = _____ ml (_._), AC = _____ ml, time = ___ min. OK (YES/NO)?

Operator Action	System Action
	The system uses patient data (entered above) and microprocessor algorithms to calculate and show the following information on the TPE values display:

- Replace volume (in milliliters) equals total replacement fluids returned to patient by replace pump. Maximum volume replaced is 9,999 ml.
- Removed volume (in milliliters) equals total plasma and anticoagulant collected in plasma bag. Maximum volume replaced is 9,999 ml. The Spectra system assumes that anticoagulant is uniformly distributed in plasma. Therefore, the amount of anticoagulant removed with plasma will vary with patient hematocrit.
- In parentheses is displayed calculated plasma volume (predetermined by using plasma volume configuration). During a procedure, this value can be changed only as a result of changing other values (replace, removed, or time).
- AC is total amount of anticoagulant used during procedure displayed in milliliters.
- Run time of procedure displayed in minutes.
- During waste divert step, anticoagulant is pumped, plasma is not collected, and replacement fluid is not pumped.

8. Approve plasma exchange results:

   - Press YES = exit patient data entry displays and continue to **Connect Patient** section.
   - Press NO = next display: change *TPE values message.*

Change: 1 = Replace volume, 2 = Removed volume, 3 = Run time, 4 = Inlet flow.

IMPORTANT: Changing one value affects other values. For instance:

Changed Value	Affected Value
Replace Volume	Removed Volume AC Flow Rate Time Inlet Volume
Removed Volume	Replace Volume AC Flow Rate Time Inlet Volume
Run Time	Replace Volume Removed Volume AC Volume Inlet Volume
Inlet Flow	Increased Inlet Flow = Shorter Run Time, Higher AC Flow Rate, and Increased AC Infusion Rate Decreased Inlet Flow = Longer Run Time, Lower AC Flow Rate, and Decreased AC Infusion Rate

Operator Action | **System Action**

9. Select TPE value to be changed:

- Press 1 = braces around replace volume
- Press 2 = braces around removed volume
- Press 3 = braces around run time
- Press 4 = braces around inlet flow
- Press 9 = redisplays *TPE fluid balance entry message* (precedes Step 7 above)

Replace = _____ ml, removed = _____ ml (__.__),
AC = _____ ml, time = ___ min. Inlet = ___.__

Operator Action	System Action

10. Using arrow keys, change selected value. The up arrow increases the value, and the down arrow key decreases it. Affected value(s) will also be changed. When satisfied that changed and affected values are appropriate, press ENTER to return to *plasma exchange results message* (follows Step 7 above). CLEAR redisplays the *change TPE values message* (follows Step 8 above).

    When changing replace volume values, the following value ranges are allowed for changed values.

Changed Value	Allowed Range
Replace Fluid Volume	100-9999 ml
Removed Volume	100-9999 ml
Run Time	10-999 min
Inlet Flow	15-150 ml/min

11. You may calculate the percent of AC in plasma bag using the following formula (where Q equals flow rate and hematocrit is entered as a fraction):

$$\frac{Q_{AC}}{(Q_{Inlet} - Q_{AC})\ (1 - \text{Hematocrit})\ + Q_{AC}} \times 100$$

OR

12. At any point during the procedure, you may review the predicted amount of AC in the plasma bag at the end of the run by following these steps:

    a. Press MENU ON/OFF key.

1 = Data Entry, 2 = Pressure Display, 3 = CCM, 4 = Air Remove, 5 = Strobe, 6 = Config., 7 = SN.

    b. Press 1 key to select "Data Entry."

Operator Action	System Action
	1 = Change procedure, 2 = Change donor information, 3 = Run results, 4 = AC data.
c. Press 4 key to display the *AC status message*.	AC infusion rate: 0.8 ml/min/liter TBV. ml AC in bags: collect:_____, plasma:_______.
	Note that the above *AC status message* provides information on the predicted number of milliters of anticoagulant in the plasma bag at the end of the run.
d. Press MENU ON/OFF key a second time to redisplay the *plasma exchange results message* (follows Step 7 above).	

Connect Patient

WARNING

Before connecting patient, check access and return lines for air. If air is present in these lines, do not connect patient. Remove air before starting procedure.

Connect access and return lines. Close access saline. Press CONTINUE to Run.

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

1. Perform venipuncture at access and return needle sites.
2. Open white pinch clamps on access and return lines.
3. Leave a saline drip on the return line to keep return needle from clotting.
4. Close roller clamp on access saline line.

Operator Action	System Action

Start Run Mode

WARNING

Monitor patient closely for reactions any time biologically derived replacement fluids are being used.

1. Press CONTINUE key to start system in Run mode.

All pumps will start and centrifuge speed will increase based on parameters preset by patient data and Spectra algorithms.

AC	Inlet	Plasma	Collect Replace	Inlet : AC Ratio	Spin RPM
__.__	___.__	___.__	___.__	___.__	_____

Diverting prime saline.

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- _______ rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

NOTE

It is normal that a small amount of red cells may be diverted to the waste bag when prime saline is diverted.

2a. If you want to divert the prime saline to the waste bag, continue with Step 3.

OR

2b. If you do not want to divert the prime saline to the waste bag and, instead, want to return it to the patient, follow these steps:

- Press the CHANGE MODE key.
- Press 3 key to select Run.
- Close the roller clamp on the return saline line. (The system will not prompt you to do this.)
- Press CONTINUE key.

Operator Action	System Action
• Continue with Step 4, but do not press CLEAR.	

```
 AC      Inlet     Plasma    Collect   Inlet : AC   Spin
                             Replace   Ratio        RPM
 __.__  ___.__  ___.__  ___.__  ___.__  _____
 Close return saline.  Press CLEAR.
```

AC Pump -- ___.__ ml/min
Inlet Pump -- ___.__ ml/min
Plasma Pump -- ___.__ ml/min
Collect Pump -- ___.__ ml/min
Ratio -- __ : 1
Centrifuge -- _______ rpm
Waste Valve -- Closed
Plasma Valve -- Variable Position
Collect Valve -- Load Position
RBC Line Valve -- Open
Return Line Valve -- Open

Audio: Operator-attention alarm sounds.

3. Use roller clamp to close the green-striped return saline line because blood flow is being returned to patient.

4. Press CLEAR key.

The Spectra system automatically establishes red cell/plasma interface and waits until 200 ml of inlet volume have been processed before removing plasma. The rate that replacement fluid is returned to the patient will be determined by the previously selected fluid balance.

The Spectra system displays pump flow rates, anticoagulant ratio, centrifuge rpm, accumulated volumes processed by each pump, procedure time (in minutes), and procedure type.

```
 AC      Inlet     Plasma    Collect   Inlet : AC   Spin
                             Replace   Ratio        RPM
 __.__  ___.__  ___.__  ___.__  ___.__  _____
 ____   _____   _____   _____   _____    TPE
                             Collect   Time     Procedure
 AC      Inlet     Plasma    Replace   Min
```

AC Pump -- ___.__ ml/min
Inlet Pump -- ___.__ ml/min
Plasma Pump -- ___.__ ml/min
Collect Pump -- ___.__ ml/min
Ratio -- __ : 1
Centrifuge -- _______ rpm
Waste Valve -- Closed
Plasma Valve -- Variable Position
Collect Valve -- Load Position
RBC Line Valve -- Open
Return Line Valve -- Open

Operator Action

System Action

5. During procedure, red cell/plasma interface should be monitored every 30 minutes to ensure red cells are not accumulating in channel. (See Figure 6A-5.)

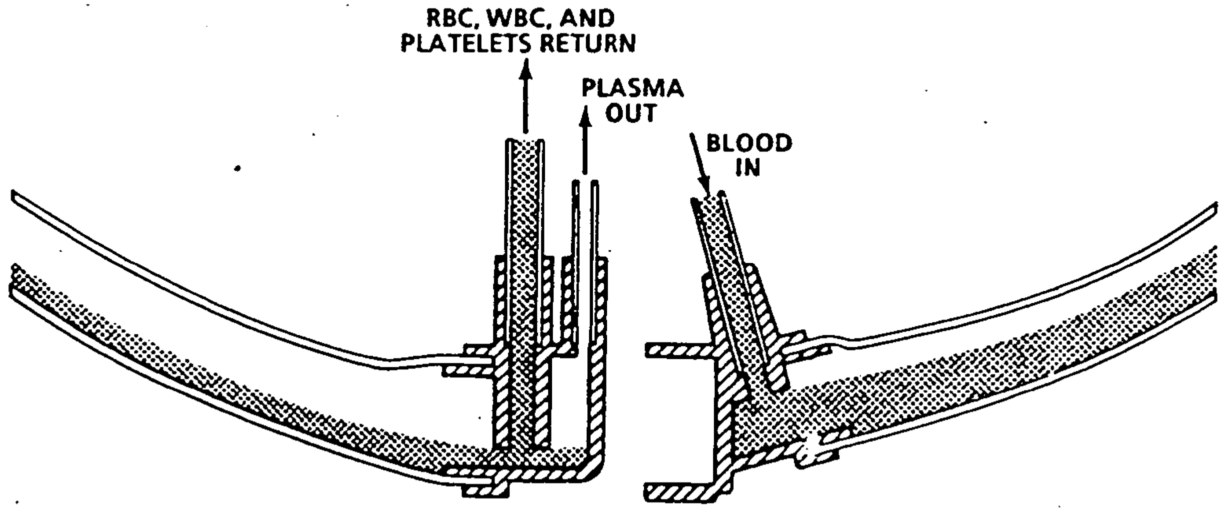

Figure 6A-5. Correct Red Cell/Plasma Interface

6. If red cells are accumulating in channel (see Figure 6A-6), perform procedure for **RED CELL ACCUMULATION IN TPE CHANNEL** in SECTION 12 – RECOVERY PROCEDURES.

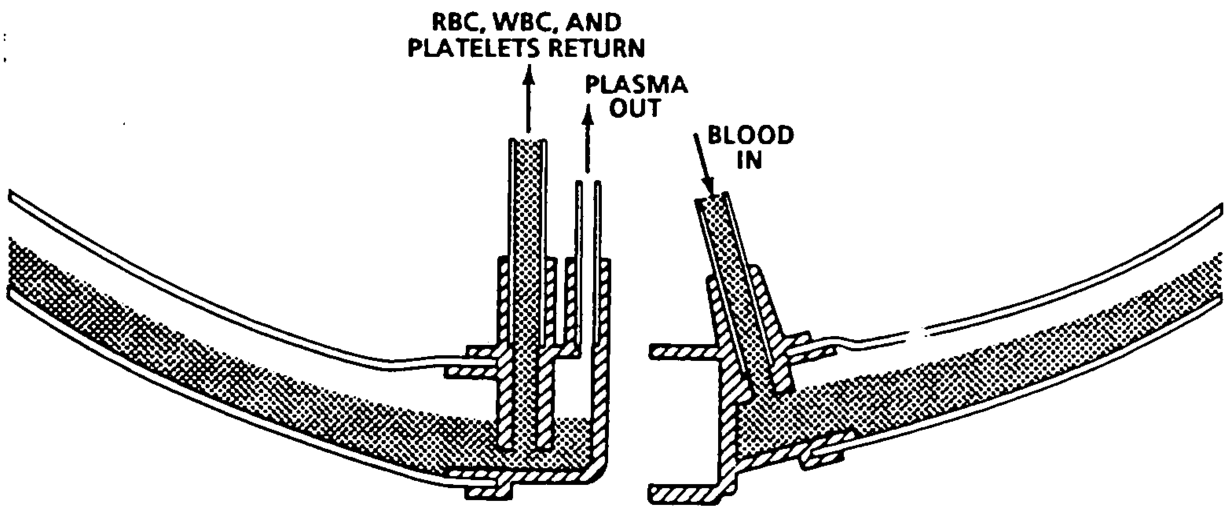

Figure 6A-6. Red Cell Accumulation in TPE Channel

Run mode continues until target values are reached.

Operator Action	System Action
	There are audio and visual warnings when Run mode is complete. The values that have exceeded their limits will be flashing.

```
End of Run:  1 = Rinseback, 2 = Continue Run.
___  ___  ___  ___  ___                    TPE
                      Collect  Time  Procedure
AC    Inlet   Plasma  Replace  Min
```

AC Pump -- ___.__ ml/min
Inlet Pump -- ___.__ ml/min
Plasma Pump -- ___.__ ml/min
Collect Pump -- ___.__ ml/min
Ratio -- __ : 1
Centrifuge -- ______ rpm
Waste Valve -- Closed
Plasma Valve -- Variable Position
Collect Valve -- Load Position
RBC Line Valve -- Open
Return Line Valve -- Open

Operator Action	System Action
7. Press 2 key to continue Run mode. (To start Rinseback mode, press 1 key and skip to **Start Rinseback Mode** section.)	If no selection is made, a shutdown alarm will occur after 10 minutes and the pumps will stop.

```
Increase flashing target limits.
___  ___  ___  ___  ___                 Target
                      Collect  Time  Procedure
AC    Inlet   Plasma  Replace  Min
```

All Pumps -- ___.__ ml/min
Ratio -- __ : 1
Centrifuge -- ______ rpm
Waste Valve -- Closed
Plasma Valve -- Variable Position
Collect Valve -- Load Position
RBC Line Valve -- Open
Return Line Valve -- Open

Operator Action	System Action
8. Select flashing target value on bottom row of display.	Inlet volume processed and time elapsed are only values that flash.
9. To increase inlet volume or time, press appropriate key.	
10. Enter new target value on numeric keypad. Then press ENTER.	Run mode continues until target values are reached. There are audio and visual warnings when Run mode is complete.

Operator Action	System Action
	End of Run: 1 = Rinseback, 2 = Continue Run. ___ ___ ___ ___ ___ TPE AC Inlet Plasma Collect/Replace Time Min Procedure

AC Pump	-- ___._ ml/min
Inlet Pump	-- ___._ ml/min
Plasma Pump	-- ___._ ml/min
Collect Pump	-- ___._ ml/min
Ratio	-- _ : 1
Centrifuge	-- ____ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Start Rinseback Mode

1. Press 1 key to start Rinseback mode.

If no selection is made, a shutdown alarm will occur after 10 minutes.

Clamp & disconnect access. Open access saline. Press CONTINUE to Rinseback.

AC Pump	-- ___._ ml/min
Inlet Pump	-- ___._ ml/min
Plasma Pump	-- ___._ ml/min
Collect Pump	-- ___._ ml/min
Ratio	-- _ : 1
Centrifuge	-- ____ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

2. Close white pinch clamp on access line. Open roller clamp on green-striped access saline line to allow saline to enter system.
3. Press CONTINUE key to start Rinseback.
4. Disconnect access needle and place in appropriate needle disposal container.

Operator Action	System Action
	Clamp and disconnect collection bags. Press CLEAR.

AC Pump	-- Stopped
Inlet Pump	-- 50.0.ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

NOTE

If the inlet flow was higher than 50 ml/min during the Run mode, the inlet pump will run at the higher rate.

5. **IMPORTANT**: Close slide clamp(s) on line(s) leading to plasma bag(s).

6. Press CLEAR to continue Rinseback.

Rinseback: Returning RBCs. Rinse.

AC Pump	-- Stopped
Inlet Pump	-- 50.0.ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 120 ml Inlet
Approximate Time	-- 144 seconds

NOTE

If the inlet flow was higher than 50 ml/min during the Run mode, the inlet pump will run at the higher rate.

Red blood cell line is only flow back to patient during this step.

Operator Action	System Action

Rinseback: Recirculating.
Rinse.

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma Pump	-- 150.0 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Recirculate Position
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Volume	-- 300 ml Plasma
Approximate Time	-- 120 seconds

The Spectra system closes return line valve and flushes red cells off channel wall by recirculating saline through channel at high speed.

NOTE

No flow to or from patient during this step

Rinseback: Evacuating channel.
Rinse.

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma Pump	-- 40.0 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 150 ml Plasma
Approximate Time	-- 225 seconds

The Spectra system opens return line valve so free red cells can be returned to patient. Channel is collapsed to reduce extracorporeal blood volume.

Operator Action | **System Action**

Rinseback: Rinsing channel. Rinse.

AC Pump	-- Stopped
Inlet Pump	-- 40.0 ml/min
Plasma Pump	-- 40.0 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 75 ml Inlet
Approximate Time	-- 90 seconds

NOTE

If the inlet flow was higher than 40 ml/min during the Run mode, the inlet pump will run at the higher rate.

The Spectra system allows additional saline to enter channel to flush final red cells back to patient.

Disconnect Patient

Rinseback completed. Disconnect return line. Close fluids. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed

1. When Rinseback mode is completed, close white pinch clamp on return line. Disconnect return needle. Close roller clamp on green-striped access saline line. Close slide clamp on replacement fluid line.

2. Press CONTINUE key.

Operator Action	System Action
	Final values. Press CONTINUE to unload. ___ ___ ___ ___ ___ ___ AC Inlet Plasma Collect/Replace Time Min Procedure All Pumps -- Stopped Centrifuge -- Stopped Waste Valve -- Load Position Plasma Valve -- Load Position Collect Valve -- Load Position RBC Line Valve -- Open Return Line Valve -- Open
3. Record on patient records final volumes processed during procedure.	

REMOVING TPE DISPOSABLES

Operator Action	System Action
(See Figure 1-13.)	
1. Place ends of patient access and return lines in appropriate biohazard disposal container.	
2. Press UNLOCK COVER key.	
3. Slide centrifuge cover back.	
4. Lower centrifuge door.	
5. Remove three-lumen tubing from exit slot on right side of system.	
6. Remove collar from upper collar holder.	
7. Remove upper bearing from upper bearing holder.	
8. Remove lower bearing from lower bearing holder.	
9. Push filler latching pin toward center of centrifuge and raise filler latch.	
10. Pull tubes from slots in filler.	
11. Pull channel from filler.	
12. Open hinged cover on centrifuge collar holder and remove collar.	
13. Raise channel above filler.	
14. Fold channel in half and pull through loading port.	
15. Discard channel in appropriate biohazard disposal container. (Channel will still be connected to tubing.)	
16. Close centrifuge door and cover.	

Operator Action	System Action

17. Remove lines from the following:

   - Collect and plasma valves
   - Return pressure sensor
   - Waste divert valve
   - RBC line valve
   - Return and inlet air detectors
   - Centrifuge pressure sensor
   - Access pressure sensor
   - Return line valve
   - Anticoagulant level detector

18. Press CONTINUE key to unload pumps.

> Unloading pumps.
> Unload

All Pumps	-- 48 ml/min
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Time	-- 7 seconds

19. Remove lines from cartridge clamps (press clamps up to release pump cartridges).

20. Remove return needle and needle in saline container from tubing set and place them in appropriate needle disposal container.

21. Remove fluid containers and waste bag from Spectra system and place in appropriate biohazard disposal container along with tubing.

> COBE Spectra (Revision __).
> Press CONTINUE to load tubing set.

6b-TPE SN
Operation

SECTION 6B - TPE SINGLE-NEEDLE OPERATION

This single-needle procedure is intended for use when a TPE Set is used to remove plasma from a patient requiring therapeutic plasma exchange. Steps are included for converting a dual-needle TPE blood tubing set to single-needle operation by the addition of a single-needle bag and "Y" connector. The "Y" connector provides for the replacement of the access and return needles with a single needle that provides both functions in a single-needle procedure. See SECTION 6A – TPE DUAL-NEEDLE OPERATION for TPE dual-needle procedure.

REQUIRED EQUIPMENT AND SUPPLIES

DUAL- AND SINGLE-NEEDLE PROCEDURES

- COBE Spectra™ Apheresis System
- Single-stage channel filler
- TPE flow path overlay
- Disposable TPE blood tubing set (Catalog Number 777005-000)
- Anticoagulant (ACD-A – each 100 ml contains: 2.2 g sodium citrate hydrous, 730 mg citric acid anhydrous, and 2.45 g dextrose hydrous). If clinical requirements make it necessary to use heparin rather than ACD-A as the anticoagulant for TPE procedures, see **HOW TO USE HEPARIN AS TPE ANTICOAGULANT** in SECTION 10 – HELPFUL HINTS.
- 0.9% sodium chloride for injection (1000 ml). When only single-port saline containers are available and/or hypersensitivity reactions associated with ethylene oxide sterilization must be avoided, see **HOW TO USE AN ALTERNATIVE SINGLE-PASS PRIME PROCEDURE** in SECTION 10 – HELPFUL HINTS.
- Replacement fluids prescribed by physician.
- Microaggregate filters for selected replacement fluids
- Forceps or hemostats

SINGLE-NEEDLE PROCEDURES ONLY

- Single-Needle Set: Single-needle bag and "Y" connector (Catalog Number 777000-100)
- Return Flow Controller (Catalog Number 951000-000)
- One needle
- Blood pressure cuff

Operator Action	System Action

Check System

1. Plug in Spectra Apheresis System.
2. Turn power switch ON.

The system will go through a short self-check to ensure that the various power supplies are operating at the correct voltage.

> Power up tests in progress.

> COBE Spectra (Program Revision __).
> Press CONTINUE to load tubing set.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- *Load Position
Plasma Valve	-- *Load Position
Collect Valve	-- *Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

*Refer to Appendix A for an explanation of valve positions.

3. Verify the following:
   - Yellow warning LED is illuminated.
   - "COBE Spectra (Revision __)" is displayed.
   - PAUSE LED is flashing.
   - Cartridge clamps are in load position.
   - Single-Needle Option is installed.
     - Press MENU ON/OFF key.
     - Press 6 to select Configuration.
     - Press ENTER key twice to reach the third configuration screen.
     - Press 3 to select "SN."
     - If the next screen says that the Single-Needle Option is not installed, press 1 to install it and press MENU ON/OFF key to remove message.

Operator Action | System Action

Install Return Flow Controller

If the Return Flow Controller is not already installed on the IV pole, install it following the instructions of the **INSTALLATION OF RETURN FLOW CONTROLLER** section of SECTION 2 – INSTALLATION.

Install Filler

1. Press UNLOCK COVER key.
2. Slide centrifuge cover back.
3. Lower centrifuge door.
4. Rotate centrifuge so centrifuge loading port (with alignment dot) is facing the front. (See Figure 6B-1.)
5. If a dual-stage channel filler is in place, remove it as follows:
   - Push filler latching pin (No. 5 in Figure 1-13) toward center of centrifuge and raise filler latch (No. 6 in Figure 1-13).
   - Push filler locking pin (No. 4 in Figure 1-13) toward center of centrifuge and raise filler.
6. Position single-stage channel filler so dots on centrifuge and filler are aligned. (See Figure 6B-1.)
7. Place filler over centrifuge assembly, and press down until filler locking pin is securely in place.
8. Lower filler latch.
9. Lift up on filler to ensure it is securely in place.
10. Close centrifuge door and cover.
11. Install TPE flow path overlay on front panel.

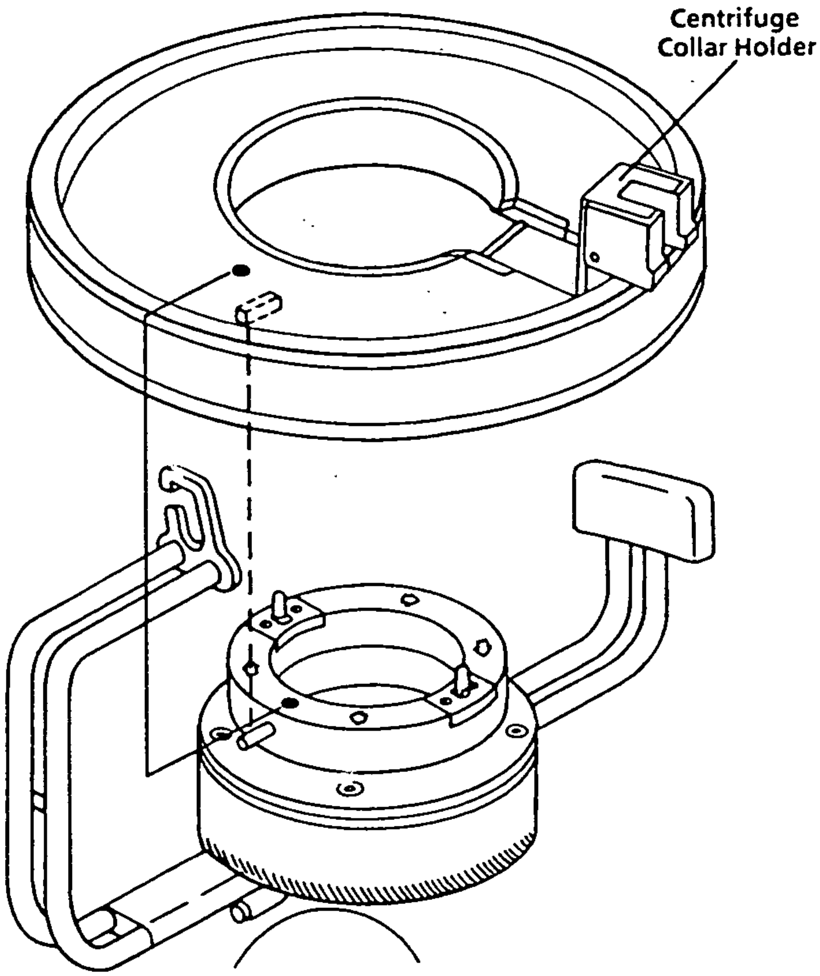

Figure 6B-1. Correct Filler/Centrifuge Alignment

Operator Action | System Action

Place Tubing on Front Panel

(See Figure 1-14.)

1. Swing control panel to the side.
2. Peel back cover on disposables package.
3. Place disposables set package on centrifuge cover.
4. Package should be held securely by placing it underneath packaging hook on front panel.
5. Remove inlet line coil and remove white paper tapes. (See Figure 6B-2.)

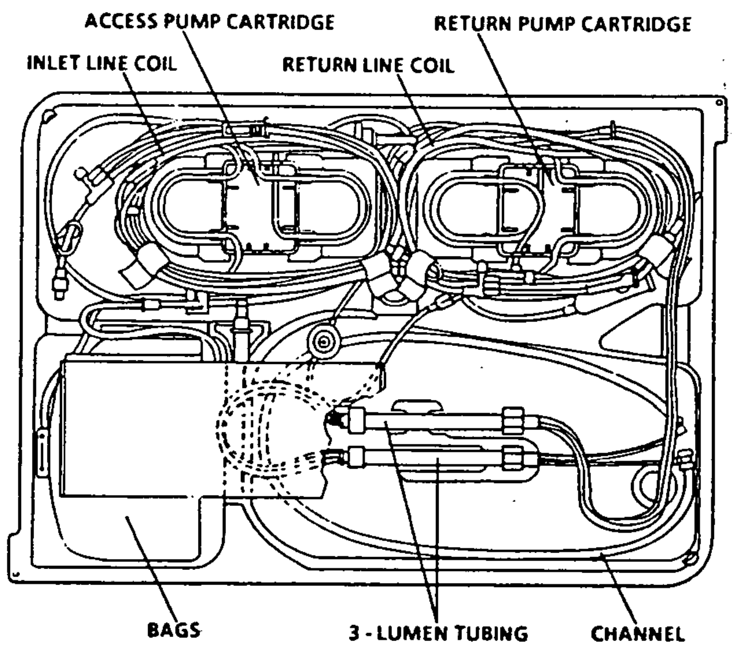

Figure 6B-2. Packaged Tubing Set

a. Hang patient connection on hook on left side of IV pole. (For identification purposes, the three lines attached to this connection are taped together with red tape until they reach the front panel.)

b. Place access saline line (green striped) over the top of the system.

Operator Action **System Action**

6. Remove return line coil and remove white paper tapes. (See Figure 6B-2.)

   a. Hang patient connection on hook on left side of IV pole. (For identification purposes, the two lines attached to this connection are taped together with blue tape until they reach the front panel.)

   b. Place return saline line over the top of the system.

7. Hang the 4-liter plasma waste bag on two side-by-side hooks on the IV pole to the right of the Return Flow Controller. Hang the prime-solution waste bag on a hook to the left of the Return Flow Controller.

8. Using aseptic technique, connect the "Y" connector to the access and return lines and the access/return needle:

   a. Remove "Y" connector from Single-Needle Set.

   b. Remove protective cap from one female port of of the "Y" connector (Figure 1-12) and connect that port to the male port on the access line.

   c. Remove protective cap from other female port on the "Y" connector and connect that port to the male port on the return line.

   d. Remove protective cap from the male port on the "Y" connector and connect that port to the access/return needle.

   e. Secure but do not overtighten all three connections.

9. Clamp accessory "Y" line on plasma line (right line in No. 15 in Figure 1-9).

10. Remove return pump cartridge and snap it into the cartridge clamp between plasma and collect/replace pump. (COBE label on cartridge should be facing up.)

11. Remove access pump cartridge and snap it into the cartridge clamp between the AC and inlet pumps. (COBE label on cartridge should be facing up.)

Operator Action	System Action
12. Place AC line over top of the system.	
13. Ensure that all tubing is clear of pumps and untangled.	
14. Press CONTINUE key to load tubing into pump housings.	Cartridge clamps are retracted and tubing headers are threaded onto pump rotors.

Loading pumps.	Load

All Pumps	-- 48 ml/min
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Collect Position
Collect Valve	-- Collect Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Time	-- 10 seconds

Operator Action	System Action
15. Verify all four pumps are loaded.	After pumps are loaded, valves automatically open to load position.

16. Put lines in collect/replace and plasma valves.

17. Lay replace solution spike assemblies over top of the system.

18. Place sensor in return pressure sensor housing. Press down and turn clockwise to lock in place.

19. Place RBC line in RBC valve. Ensure line is completely inserted in RBC detector.

20. Position return and inlet air chambers in air detectors with air chamber filters located below air detector housings. Ensure waste divert lines are toward you.

21. Put lines in waste valve assembly.

22. Place line in centrifuge pressure sensor housing. Use a "flossing" action to ensure line is completely inserted in pressure sensor.

23. Place sensor in access pressure sensor housing. Push down and turn clockwise to lock in place.

24. Position return line in return valve so line runs horizontally through center of valve.

25. Release three-lumen tubing from package retainers.

Operator Action | System Action

Install Single-Needl Bag

1. Place Return Flow Controller into Load position by turning its flow control hand-crank (Figure 1-16) all the way counter-clockwise to the Load position. (See Figure 1-18.)

2. Remove the single-needle bag from the Single-Needle Set and load it into the space that Step 1 created at the top of the Return Flow Controller:

NOTE

The single-needle bag is symmetrical and may be loaded with either side up.

a. Hold bag in your right hand so that the end with the locator hole (Figure 1-12) is pointing toward your left.

b. Loosely fold the bag in half lengthwise to facilitate its insertion into the Return Flow Controller.

c. Insert the locator hole end of the bag into the right side of the space made at the top of the Return Flow Controller by Step 1.

d. Grasp the bag's load tab through the Return Flow Controller's left side access port and place the bag's locator hole over the bag locator pin on the bag mounting plate. (See Figure 1-16.)

e. Ensure that the bag is lying flat on the plate.

f. Place the bag's tubes on either side of the bag alignment block.

3 Using aseptic technique, connect the single-needle reservoir bag to the TPE blood tubing set:

a. Connect male luer lock (No. 29 above return air chamber in Figure 1-9) of TPE set to female port of single-needle bag.

b. Connect female luer lock of TPE set to male port of single-needle bag.

Operator Action | System Action

c. Secure but do not overtighten both connections.

Install Channel in Centrifuge

(See Figure 1-13.)

1. Remove channel (Figure 6B-2) from package.
2. Discard package.
3. Press UNLOCK COVER key.
4. Slide centrifuge cover back.
5. Lower centrifuge door.
6. Rotate centrifuge so loading port (No. 8 in Figure 1-13) is open to the front.
7. Ensure that centrifuge collar holder is resting on the outer rim of the filler. (See position of centrifuge collar holder in Figure 6B-1.) If centrifuge collar holder is not resting on the outer rim of the filler, push filler latching pin (No. 5 in Figure 1-13) toward center of centrifuge, raise filler latch (No. 6 in Figure 1-13), and place it on the outer rim.
8. Extend centrifuge loop to full length to ensure three-lumen tubing is not twisted.
9. Fold channel in half.
10. Thread channel through lower loading port and pull it out from the top.
11. Position channel in correct orientation above filler slots before placing centrifuge collar (Figure 6B-3) into centrifuge collar holder (Figure 6B-1).
12. Load centrifuge collar into centrifuge collar holder, closing cover over collar.
13. Lower filler latch into locked position.

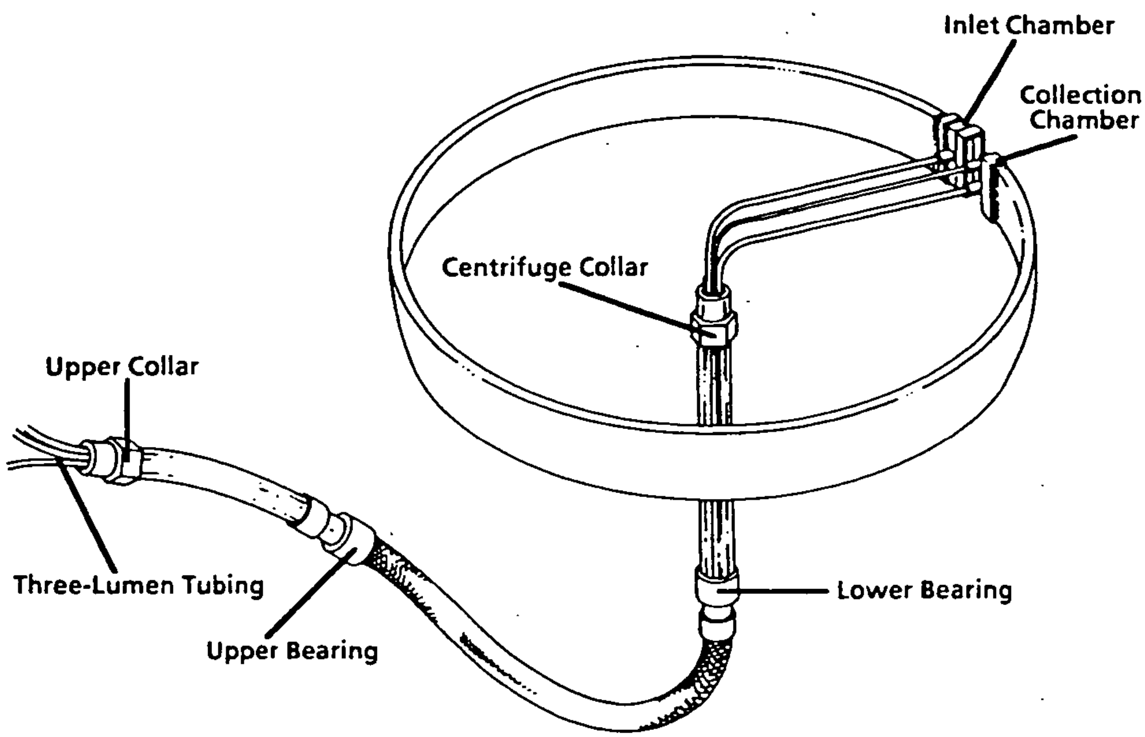

Figure 6B-3. TPE Single-Stage Channel

Operator Action	System Action
14. Press channel into position, ensuring it is completely loaded in filler. Start at collection chamber and work toward inlet chamber (Figure 6B-3).	
15. Press tubes into appropriate slots in filler, ensuring all tubes are completely inserted.	
16. Place lower bearing (Figure 6B-3) in lower bearing holder (No. 10 in Figure 1-13).	
17. Place upper bearing (Figure 6B-3) in upper bearing holder (No. 11 in Figure 1-13).	

Operator Action	System Action
18. Place upper collar (Figure 6B-3) in upper collar holder (No. 12 in Figure 1-13). Ensure collar is held securely by visually checking that both black sides of holder are equally closed around collar and that an edge between two of the upper collar's six sides is facing out. Be sure that one of the upper collar's six sides is *not* facing out. See Figure 6B-4.	

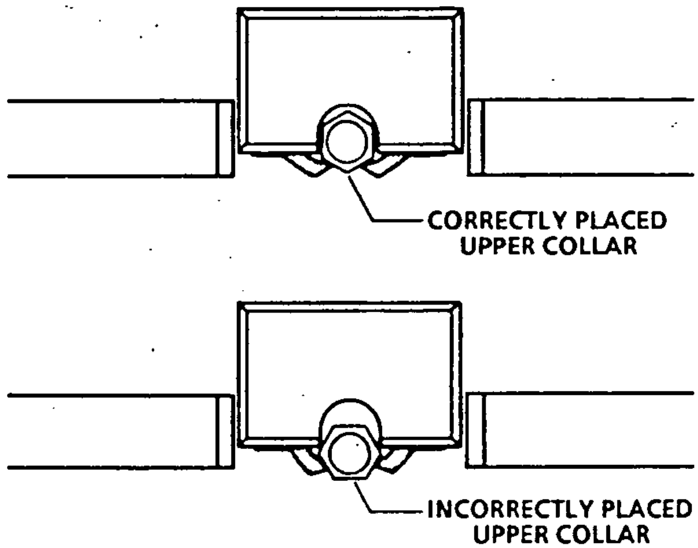

Figure 6B-4. Upper Collar Placement

19. Use a "flossing" action to place three-lumen tubing in exit slot on right side of the system.

20. Rotate centrifuge several times to ensure tubing does not twist and upper bearing remains in place.

> **WARNING**
>
> **Inspect all lines, especially those in the centrifuge and on the front panel, to ensure they are not kinked. Lines that are occluded, or partially occluded, may lead to fluid imbalance.**

21. Close centrifuge door and cover.

Operator Action | **System Action**

Prime Tubing Set

(See Figure 1-9.)

When only single-port saline containers are available and/or hypersensitivity reactions associated with ethylene oxide sterilization must be avoided, see **HOW TO USE AN ALTERNATIVE SINGLE-PASS PRIME PROCEDURE** in SECTION 10 – HELPFUL HINTS. The single-pass prime procedure can also be used with single-needle TPE procedures.

> Select set: 1 = Platelets or ELP,
> 2 = TPE, 3 = WBC, 4 = RBCX.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

1. Press 2 key to select TPE tubing set.

   If you make a mistake and enter the wrong set number:

   - Press the CHANGE MODE key.
   - Press 1 key to select Load Set.
   - Press the 2 key to select the TPE blood tubing set and continue with Step 2.

If the Single-Needle Option is installed, this message is displayed:

> Select:
> 1 = Single needle, 2 = Dual needle.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Operator Action	System Action
2. Press 1 key to select "Single needle."	

When Single-Needle Option is selected in Step 2, this message is displayed.

> Set return flow scale to prime.
> Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

3. Place Return Flow Controller in Prime position by cranking its flow control handcrank (Figure 1-16) clockwise until it can no longer turn. (See Figure 1-18.) Do not use excessive force when cranking the handcrank.

4. Verify that the single-needle bag is pressed flat between the plates of the Return Flow Controller and that the lines leaving the right side of the bag are not kinked or twisted.

5. Press CONTINUE key.

> Clamp access and return lines.
> Close both saline lines. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

6. Close white pinch clamps on access and return lines near luer connections. Close roller clamps on access and return saline lines.

7. Press CONTINUE key.

Operator Action	System Action
	Connect TPE tubing set to AC, saline, & replacement containers. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

CAUTION

Use aseptic technique throughout this procedure.

8. Connect AC line to anticoagulant container, and place AC line in AC level detector.

NOTE

If clinical requirements make it necessary to use heparin rather than ACD-A as the anticoagulant for TPE procedures, see **HOW TO USE HEPARIN AS TPE ANTICOAGULANT** in SECTION 10 – HELPFUL HINTS.

9. Connect inlet and return saline lines to same saline container. Using aseptic technique, clean injection port before inserting metal spike into it. Then place plastic spike in spike port (after removing cover). Fill drip chambers 1/2 full.

CAUTION

Ensure lines are attached to correct fluids:

1. AC line to anticoagulant container.

2. Access and return saline lines to normal saline container.

Visually verify that fluid is flowing into the access, return, and AC drip chambers.

10. Connect replace solution spikes to replacement fluids prescribed by physician. (Microaggregate filters may be used for selected replacement fluids, for example, fresh frozen plasma. Ensure filters are primed before use if required by manufacturer's instructions.) Fill drip chambers 1/2 full.

Operator Action | System Action

WARNING

Fluid imbalances can be caused by the following:

1. Using inadequately primed or clotted microaggregate filters used on replacement line.
2. Administering replacement fluids that are not at room temperature.
3. Using improperly vented replacement fluid containers.
4. Equipment malfunction.
5. Improper line clamping.

Monitor all solutions and procedures for correct fluid balance.

WARNING

The addition of calcium gluconate or other calcium salts to fresh frozen plasma may cause clotting in the replacement fluid.

Blood components containing formed elements are not recommended as replacement fluids.

11. Press CONTINUE key.

Open access and return saline lines.
Press CONTINUE to prime.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

Operator Action	System Action

WARNING

Once fluid has entered the tubing set, do not disturb sensors in pressure sensor housings because this will prevent transducers from monitoring pressures accurately. (See SECTION 12 - RECOVERY PROCEDURES for information on how to load pressure sensors with fluid in the tubing set.)

12. Open access and return saline roller clamps.

13. Press CONTINUE key to prime tubing set.

If the Spectra system was not turned off after the last procedure, it will go through a short self-check before beginning Prime.

> Power up tests in progress.

> Priming anticoagulant line.
> (TPE Set) Prime

AC Pump	-- 100 ml/min
Inlet Pump	-- Stopped
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Inlet Divert Position
Plasma Valve	-- Collect Position
Collect Valve	-- Collect Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- 30 ml AC
Approximate Time	-- 18 seconds

14. Patient data can be entered before tubing set is primed, during Prime mode, or after priming is complete.
    a. To enter patient data before Prime mode, select set type (2 = TPE) and press MENU ON/OFF key. Continue with Step 14d.
    b. To enter patient data during Prime mode, press MENU ON/OFF key. Continue with Step 14d.
    c. To enter patient data after priming is complete, continue with Step 15.
    d. Press 1 key to select "Data Entry." (Refer to following section, **Enter Patient Data**, for instructions on how to enter patient information.)

Operator Action	System Action

> Priming inlet line and air chamber.
> (TPE Set) Prime

AC Pump	-- Stopped
Inlet Pump	-- 150 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Inlet Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Volume	-- Fluid in Inlet Air Chamber Plus 25 ml
Approximate Time	-- 48 seconds

This step pumps saline through the access saline line, inlet line, and inlet air chamber. To prime the waste line, saline flows for a short time after fluid is detected in the inlet air chamber.

> Testing sensors, valves, and pumps.
> Prime

AC Pump	-- Stopped
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Varies Flow Rate
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Varies Position
Approximate Time	-- 51 seconds

Several valves change position as the system does a series of self-checks to ensure front panel components have been loaded correctly.

> Priming centrifuge channel.
> Prime

AC Pump	-- Stopped
Inlet Pump	-- 150 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 100 ml Inlet
Approximate Time	-- 40 seconds

Operator Action	System Action

Priming centrifuge channel. Prime

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma Pump	-- 150 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 250 ml Plasma
Approximate Time	-- 100 seconds

Priming centrifuge channel. Prime

AC Pump	-- Stopped
Inlet Pump	-- 120 ml/min
Plasma Pump	-- 120 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 82 ml Inlet
Approximate Time	-- 41 seconds

Priming centrifuge channel. Prime

AC Pump	-- Stopped
Inlet Pump	-- 120 ml/min
Plasma Pump	-- 120 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 200 ml Inlet
Approximate Time	-- 100 seconds

Operator Action	System Action

Testing sensors, valves, and pumps. Prime

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma Pump	-- Stopped
Collect Pump	-- Varies Flow Rate
Centrifuge	-- 1200 rpm
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Time	-- 12 seconds

Priming return air chamber. Prime

AC Pump	-- 12.5 ml/min
Inlet Pump	-- 150 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- 30 ml/min
Centrifuge	-- 800 rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- Fluid in Return Air Chamber Plus 25 ml
Approximate Time	-- 48 seconds

Priming return lines. Prime

AC Pump	-- 12.5 ml/min
Inlet Pump	-- 150 ml/min
Plasma Pump	-- 100 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 50 ml Inlet
Approximate Time	-- 20 seconds

Operator Action	System Action

System Action

Testing sensors, valves, and pumps. Prime

AC Pump	-- Varies Flow Rate
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Varies Flow Rate
Collect Pump	-- Varies Flow Rate
Centrifuge	-- Varies
Waste Valve	-- Varies Position
Plasma Valve	-- Varies Position
Collect Valve	-- Varies Position
RBC Line Valve	-- Varies Position
Return Line Valve	--Varies Position
Approximate Time	-- 70 seconds

The various valves and pumps change position as the Spectra system removes air from the channel and does a series of self-checks.

Priming single needle bag. Prime

All Pumps	-- Vary Flow Rate
Centrifuge	-- Varies
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Varies Position
Return Line Valve	-- Varies Position

Prime access and return connections. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Operator Action

15. If there is a needle clamp, ensure it is open.

16. Open white return pinch clamp near return line connection to "Y" connector. Allow saline to fill luer lock connection and "Y" arm by gravity. Close white return line pinch clamp.

17. Open white access pinch clamp near access line connection to "Y" connector. Allow saline to fill luer lock connection, "Y" arm, and needle by gravity. Close white access pinch clamp. Close white needle pinch clamp.

Operator Action	System Action
18. Press CONTINUE key.	

> Close access saline line. Clamp access line. Press CONTINUE to test AC ratio.

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

19. Use roller clamp to close green-striped access saline line, close white access pinch clamp, and press CONTINUE to test the AC ratio.

> Testing AC ratio.
> Prime

AC Pump	-- Varies Flow Rate
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Time	-- 11 seconds

The AC and inlet pumps change flow rates as the Spectra system does a series of self-checks.

> WARNING: Do not connect donor/patient before running Alarm Tests. CONTINUE.

20. Press CONTINUE key to clear this warning from screen.

Operator Action	System Action
	Perform alarm tests (YES/NO)?

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Time	-- 9 seconds

21. Press YES key to run semiautomatic alarm tests. Refer to SECTION 9 – DIAGNOSTICS for **ALARM TESTS** procedure.

At this point the Spectra system provides an opportunity to verify that key alarm systems are fully operational. Alarm tests will check operation of access pressure sensor, return air detector, return pressure sensor, fluid leak detector, and centrifuge door and cover safety system.

NOTE

To clear saline from return saline drip chamber (so saline drip can be observed), do the following:

1. Clamp line below chamber.
2. Invert container and squeeze saline from drip chamber into saline container.
3. Rehang saline container.
4. Remove clamp.

22. Continue with **Enter Patient Data** steps.

Enter Patient Data

The Spectra system will customize therapeutic plasma exchange procedures by using patient data to calculate pump flow rates, centrifuge speed, remove/ replace volumes, and procedure time. All therapeutic plasma exchange procedures have a default inlet:AC ratio of 10:1.

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Operator Action	System Action
	Select sex: 1 = Male, 2 = Female. (ENTER = Male)
1. Enter patient sex: • Press 1 if male. • Press 2 if female. • Press ENTER for default (data in parentheses).	
	(English units - enter feet): Enter height, in feet: {0} , and/or inches: 0 (Range: 1 to 7 feet)
2. Enter patient height:	

Feet and Inches	Inches	Centimeters
_ feet plus ENTER then _ inches plus ENTER	ENTER then _ inches plus ENTER	_ centimeters plus ENTER
Range: 1-7 ft	Range: 12-84 in.	Range: 30-220 cm

Operator Action	System Action
	(English units): Enter weight, in pounds: {0} (Range: 10 to 500 lbs)
3. Enter patient weight in pounds (or kilograms). Then press ENTER.	
	Total blood volume = ________ ml. (_____ in, _____ lbs, Female). OK (YES/NO)? To confirm input, the Spectra system displays estimated total blood volume and patient data. Total blood volume is calculated from patient data entered into system. The second line of display reviews data input: height, weight, and sex.

Operator Action	System Action
4. Confirm patient data input:	
• Press NO one time = weight entry display. Press NO two times = height entry display. Press NO three times = sex entry display. • Press YES = next display: hematocrit entry.	
	Enter hematocrit (%): {41} (Range: 10% to 70%)
5. Enter hematocrit as a whole number. (Decimal point is not required.) Then press ENTER.	The Spectra system will use default values of 45% for males and 41% for females.
	Replacement fluid: 1 = Albumin/Saline, 2 = Plasma. (ENTER = Albumin/Saline)
6. Enter type of replacement fluid to be used:	The Spectra control program adjusts AC and inlet pump flow rates based on type of replacement fluid chosen. These flows are designed to minimize citrate reactions in patients.
• Press 1 if albumin/saline.	Albumin/saline replacement fluid. If calcium supplements are added to replacement fluids, higher inlet flow rates may be possible. For this selection, the AC infusion rate starts at 0.6 ml/min/liter of TBV.
• Press 2 if plasma.	Plasma replacement fluid derived from human plasma requires a slower infusion rate due to anticoagulant found in the fluid and potential allergic reactions at rapid infusion rates. For this selection the AC infusion rate starts at 0.8 ml/min/liter of TBV. When a new inlet flow rate is selected, the AC infusion rate will change to adjust to that inlet flow rate.

NOTE

If you change replacement fluid during the Run Mode, you may select the replacement fluid selection message again and change the replacement fluid selection. The Spectra system will automatically adjust the flow rates and procedure end points to reflect this change.

- Press ENTER for default (data in parentheses), which is initially albumin/saline.

Operator Action	System Action
	Enter fluid balance desired: {100}% (Range: 75% to 150%)
7. Either press ENTER to accept the default value of 100% or use the arrow keys to change to a value between 75% and 150%. Then press ENTER.	The Spectra system defines TPE fluid balance as combined infusion rates (replace flow plus AC flow) divided by plasma pump flow rate and multiplied by 100 as follows:

$$\textit{Percentage} = \frac{\textit{Replace Rate} + \textit{AC Rate}}{\textit{Plasma Pump Flow Rate}} \times 100$$

The system's calculation of fluid balance does not include approximately 150 ml of volume removed from patient during waste divert and approximately 345 ml of saline returned to patient during rinseback. Therefore, at 100% fluid balance, the system will leave patient volume expanded by 195 ml of saline.

The system calculates fluid balance, not plasma balance. For a plasma balance, amount of anticoagulant removed with plasma needs to be subtracted from the removed volume. See Step 11 for information on how to calculate the percent of anticoagulant in the plasma bag, and Step 12 for information on how to access the screen that displays the amount of anticoagulant currently in the plasma bag at any point during the procedure.

Replace = _____ml, removed = _____ml (__.__),   AC = _____ml, time = ___min. OK (YES/NO)?

The system uses patient data (entered above) and microprocessor algorithms to calculate and show the following information on the TPE values display:

- Replace volume (in milliliters) equals total replacement fluids returned to patient by replace pump. Maximum volume replaced is 9,999 ml.

- Removed volume (in milliliters) equals total plasma and anticoagulant collected in plasma bag. Maximum volume replaced is 9,999 ml. The Spectra system assumes that anticoagulant is uniformly distributed in plasma. Therefore,the amount of anticoagulant removed with the plasma will vary with patient hematocrit.

Operator Action

System Action

- In parentheses is displayed calculated plasma volume (predetermined by using plasma volume configuration). During a procedure, this value can be changed only as a result of changing other values (replace, removed, or time).
- AC is total amount of anticoagulant used during procedure displayed in milliliters.
- Run time of procedure displayed in minutes.
- During waste divert step, anticoagulant is pumped, plasma is not collected, and replacement fluid is not pumped.

8. Approve plasma exchange results:

   - Press YES = exit patient data entry displays and continue to **Connect Patient** section.
   - Press NO = next display: change *TPE values message*.

Change: 1 = Replace volume, 2 = Removed volume, 3 = Run time, 4 = Inlet flow.

IMPORTANT: Changing one value affects other values. For instance:

Changed Value	Affected Value
Replace Volume	Removed Volume AC Flow Rate Time Inlet Volume
Removed Volume	Replace Volume AC Flow Rate Time Inlet Volume
Run Time	Replace Volume Removed Volume AC Volume Inlet Volume
Inlet Flow	Increased Inlet Flow = Shorter Run Time, Higher AC Flow Rate, and Increased AC Infusion Rate Decreased Inlet Flow = Longer Run Time, Lower AC Flow Rate, and Decreased AC Infusion Rate

Operator Action	System Action
9. Select TPE value to be changed: • Press 1 = braces around replace volume • Press 2 = braces around removed volume • Press 3 = braces around run time • Press 4 = braces around inlet flow • Press 9 = redisplays *TPE fluid balance entry message* (precedes Step 7 above)	Replace = _____ml, removed = _____ml (_._), AC = _____ml, time = ___min. Inlet = ___._

Operator Action	System Action

10. Using arrow keys, change selected value. The up arrow increases the value, and the down arrow key decreases it. Affected value(s) will also be changed. When satisfied that changed and affected values are appropriate, press ENTER to return to *plasma exchange results message* (follows Step 7 above). CLEAR redisplays the *change TPE values message* (follows Step 8 above).

    When changing replace volume values, the following value ranges are allowed for changed values:

Changed Value	Allowed Range
Replace Fluid Volume	100-9999 ml
Removed Volume	100-9999 ml
Run Time	10-999 min
Inlet Flow	15-60 ml/min

11. You may calculate the percent of AC in plasma bag using the following formula (where Q equals flow rate and hematocrit is entered as a fraction):

$$\frac{Q_{AC}}{(Q_{Inlet} - Q_{AC})\ (1 - \text{Hematocrit})\ +\ Q_{AC}} \times 100$$

OR

12. At any point during the procedure, you may review the predicted amount of AC in the plasma bag at the end of the run by following these steps:

    a. Press MENU ON/OFF key.

System Action
1 = Data Entry, 2 = Pressure Display, 3 = CCM, 4 = Air Remove, 5 = Strobe, 6 = Config., 7 = SN.

    b. Press 1 key to select "Data Entry."

Operator Action	System Action
	1 = Change procedure, 2 = Change donor information, 3 = Run results, 4 = AC data.
c. Press 4 key to display the *AC status message*.	AC infusion rate: 0.8 ml/min/liter TBV. ml AC in bags: collect:_____, plasma:_______.
	Note that the above *AC status message* provides information on the predicted number of milliters of anticoagulant in the plasma bag at the end of the run.
d. Press MENU ON/OFF key a second time to redisplay the *plasma exchange results message* (follows Step 7 above).	

Connect Patient

WARNING

Before connecting patient, check access and return lines for air. If air is present in these lines, do not connect patient. Remove air before starting procedure.

Close access and return saline lines. Connect patient. Press CONTINUE to Run.

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

1. Close roller clamps on access and return saline lines. Close white pinch clamps on access and return lines.
2. Perform venipuncture at needle site.
3. Open white pinch clamp on access line.

Operator Action	System Action
4. To improve antecubital access flow, maintain a cuff pressure of between 10 and 20 mmHg on the access/return arm.	

Start Run Mode

WARNING

Monitor the patient closely for reactions any time biologically derived replacement fluids are being used.

1. Press CONTINUE key to start system in Run mode.

All pumps will start and centrifuge speed will increase based on parameters preset by patient data and Spectra algorithms.

AC	Inlet	Plasma	Collect Replace	Inlet . AC Ratio	Spin RPM
_._	___._	___._	___._	___._	_____

Diverting prime saline.

AC Pump	-- ___._	ml/min
Inlet Pump	-- ___._	ml/min
Plasma Pump	-- ___._	ml/min
Collect Pump	-- ___._	ml/min
Ratio	-- _ : 1	
Centrifuge	-- ______	rpm
Waste Valve	-- Return Divert Position	
Plasma Valve	-- Return Position	
Collect Valve	-- Load Position	
RBC Line Valve	-- Open	
Return Line Valve	-- Closed	

NOTE

It is normal that a small amount of red cells may be diverted to the waste bag when prime saline is diverted.

2a. If you want to divert the prime saline to the waste bag, continue with Step 3.

OR

2b. If you do not want to divert the prime saline to the waste bag and, instead, want to return it to the patient, follow these steps:

- Press the CHANGE MODE key.

Operator Action	System Action
• Press 3 key to select Run. • Press CONTINUE key. • Continue with Step 3.	

Set return flow scale to _____.
Open return line. Press CONTINUE.

AC Pump	-- ___._ ml/min
Inlet Pump	-- ___._ ml/min
Plasma Pump	-- ___._ ml/min
Collect Pump	-- ___._ ml/min
Ratio	-- _ : 1
Centrifuge	-- ______ rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	--Closed

Audio: Operator-attention alarm sounds.

All pump speeds, the centrifuge speed, and plasma and collect valve positions are set by alogrithms.

3. Note the number on the screen above. Turn flow control handcrank on Return Flow Controller (Figure 1-16) counterclockwise until the return flow indicator points to that number on the return flow scale (Figure 1-18).

4. Open the white pinch clamp on the return line above the "Y" connector and close roller clamp on return saline line.

5. Press CONTINUE key.

When the single-needle return phase is reached, the Return Flow Controller will apply the appropriate pressure to the single-needle bag to return the blood components withdrawn during the single-needle draw phase back to the donor at the correct flow rate.

The Spectra system automatically establishes red cell/plasma interface and and waits until 200 ml of inlet volume have been processed before removing plasma. The rate that replacement fluid is returned to patient will be determined by previously selected fluid balance.

Operator Action | **System Action**

While the interface is being established, the pumps run slower than the displayed average flow rates. Once the interface is established, the pumps speed up to approximately double the displayed average flow rates. If you get a "CENTRIFUGE PRESSURE HIGH!" alarm at this point, the instantaneous inlet flow rate may be too high. Lower the average inlet flow rate. For additional information on this alarm, see its entry in SECTION 11 - TROUBLESHOOTING.

The Spectra system displays pump flow rates, anticoagulant ratio, centrifuge rpm, accumulated volumes processed by each pump, procedure time (in minutes), and procedure type. For single-needle procedures, average flow rates are displayed.

AC	Inlet	Plasma	Collect Replace	Inlet · AC Ratio	Spin RPM
__.__	___.__	___.__	___.__	___.__	_____
____	____	____	____	____	SNTPE
AC	Inlet	Plasma	Collect Replace	Time Min	Procedure

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- _ : 1
Centrifuge	-- _______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

The system limits the average inlet flow rate to 60 ml/min for single-needle TPE procedures.

During a draw phase of a single-needle TPE procedure, a "D" will appear in the upper left-hand corner of the display screen. During a return phase, an "R" will appear.

6. To monitor instantaneous draw phase flow rates:

   a. Press MENU ON/OFF key.

1 = Data Entry, 2 = Pressure Display, 3 = CCM, 4 = Air Remove, 5 = Strobe, 6 = Config., 7 = SN.

   b. Press 7 key to select "SN" and display the single-needle instantaneous message.

Operator Action	System Action
c. Press MENU ON/OFF key to leave the single-needle instantaneous message and redisplay the Spectra TPE procedure message.	
d. If necessary, press the INLET FLOW key to reduce the inlet flow rate to ensure that none of the peak flow rates exceed 150 ml/min.	
7. During procedure, red cell/plasma interface should be monitored every 30 minutes to ensure red cells are not accumulating in channel. (See Figure 6B-5.)	

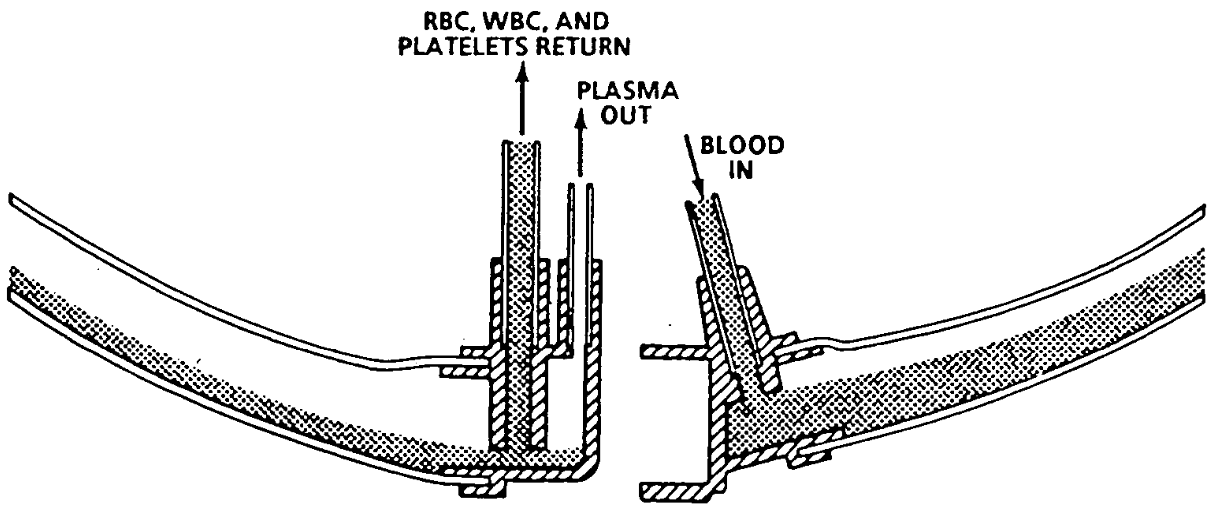

Figure 6B-5. Correct Red Cell/Plasma Interface

Operator Action	System Action
8. If red cells are accumulating in channel (see Figure 6B-6), perform procedure for RED CELL ACCUMULATION IN TPE CHANNEL in SECTION 12 – RECOVERY PROCEDURES.	
	Run mode continues until target values are reached. There are audio and visual warnings when Run mode is complete. The values that have exceeded their limits will be flashing.

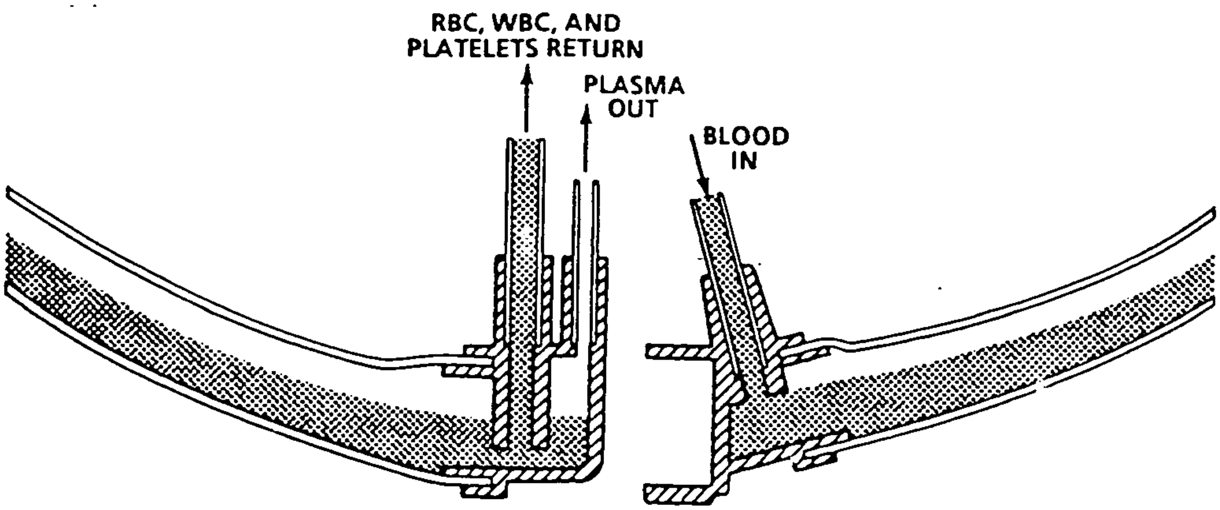

Figure 6B-6. Red Cell Accumulation in TPE Channel

Operator Action

System Action

```
End of Run:  1 = Rinseback, 2 = Continue Run.
____   ____   ____   ____   ____   SNTPE
```

AC	Inlet	Plasma	Collect / Replace	Time Min	Procedure

AC Pump -- ___.__ ml/min
Inlet Pump -- ___.__ ml/min
Plasma Pump -- ___.__ ml/min
Collect Pump -- ___.__ ml/min
Ratio -- __ : 1
Centrifuge -- ______ rpm
Waste Valve -- Closed
Plasma Valve -- Variable Position
Collect Valve -- Load Position
RBC Line Valve -- Open
Return Line Valve -- Open

9. Press 2 key to continue Run mode. (To start Rinseback mode, press 1 key and skip to **Start Rinseback Mode** section.)

If no selection is made, a shutdown alarm will occur after 10 minutes and the pumps will stop.

```
Increase flashing target limits.
____   ____   ____   ____   ____   Target
```

AC	Inlet	Plasma	Collect / Replace	Time Min	Procedure

All Pumps -- ___.__ ml/min
Ratio -- __ : 1
Centrifuge -- ______ rpm
Waste Valve -- Closed
Plasma Valve -- Variable Position
Collect Valve -- Load Position
RBC Line Valve -- Open
Return Line Valve -- Open

Operator Action	System Action
10. Select flashing target value on bottom row of display.	Inlet volume processed and time elapsed are only values that flash.
11. To increase inlet volume or time, press appropriate key.	
12. Enter new target value on numeric keypad. Then press ENTER.	Run mode continues until target values are reached. There are audio and visual warnings when Run mode is complete.

```
End of Run:  1 = Rinseback, 2 = Continue Run.
____   ____   ____   ____   ____        SNTPE
```

AC	Inlet	Plasma	Collect Replace	Time Min	Procedure

AC Pump	-- ___._ ml/min
Inlet Pump	-- ___._ ml/min
Plasma Pump	-- ___._ ml/min
Collect Pump	-- ___._ ml/min
Ratio	-- _ : 1
Centrifuge	-- ______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Start Rinseback Mode

Operator Action	System Action
1. Press 1 key to start Rinseback mode.	If no selection is made, a shutdown alarm will occur after 10 minutes.

```
Clamp access.  Open access saline.
Press CONTINUE to Rinseback.
```

AC Pump	-- ___._ ml/min
Inlet Pump	-- ___._ ml/min
Plasma Pump	-- ___._ ml/min
Collect Pump	-- ___._ ml/min
Ratio	-- _ : 1
Centrifuge	-- ______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

2. Close white pinch clamp on the access line below "Y" connector. Open roller clamp on green-striped access saline line to allow saline to enter the system.

3. Press CONTINUE key to start Rinseback and continue with Step 4.

Operator Action	System Action
	Clamp and disconnect collection bags. Press CLEAR.

AC Pump	-- Stopped
Inlet Pump	-- 50.0.ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

NOTE

If the average inlet flow was higher than 50 ml/min during the Run mode, the inlet pump will run at the higher rate.

4. **IMPORTANT**: Close slide clamp(s) on line(s) leading to plasma bag(s).
5. Press CLEAR to continue Rinseback.

Rinseback: Returning RBCs.
Rinse.

AC Pump	-- Stopped
Inlet Pump	-- 50.0.ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 120 ml Inlet
Approximate Time	-- 144 seconds

NOTE

If the average inlet flow was higher than 50 ml/min during the Run mode, the inlet pump will run at the higher rate.

Red blood cell line is only flow back to patient during this step.

Operator Action	System Action

Rinseback: Recirculating. Rinse.

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma Pump	-- 150.0 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Recirculate Position
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Volume	-- 300 ml Plasma
Approximate Time	-- 120 seconds

The Spectra system closes return line valve and flushes red cells off channel wall by recirculating saline through channel at high speed.

NOTE

No flow to or from patient during this step.

Rinseback: Evacuating channel. Rinse.

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma Pump	-- 40.0 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 150 ml Plasma
Approximate Time	-- 225 seconds

The Spectra system opens return line valve so free red cells can be returned to patient. Channel is collapsed to reduce extracorporeal blood volume.

Operator Action

System Action

> Rinseback: Rinsing channel.
> Rinse.

AC Pump	-- Stopped
Inlet Pump	-- 40.0 ml/min
Plasma Pump	-- 40.0 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 75 ml Inlet
Approximate Time	-- 90 seconds

NOTE

If the average inlet flowwas higher than 40 ml/min during the Run mode, the inlet pump will run at the higher rate.

The Spectra system allows additional saline to enter channel to flush final red cells back to patient.

Disconnect Patient

> Rinseback completed. Disconnect return line. Close fluids. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed

1. When Rinseback mode is completed, close white pinch clamp on return line. Disconnect access/return needle. Close roller clamp on green-striped access saline line. Close slide clamp on replacement fluid line.
2. Press CONTINUE key.

Operator Action	System Action
	Final values. Press CONTINUE to unload. ___ ____ ____ ____ ____ ____ AC Inlet Plasma Collect/Replace Time Min Procedure
	All Pumps -- Stopped Centrifuge -- Stopped Waste Valve -- Load Position Plasma Valve -- Load Position Collect Valve -- Load Position RBC Line Valve -- Open Return Line Valve -- Open
3. Record on patient records final volumes processed during procedure.	

REMOVING TPE DISPOSABLES

Operator Action	Sy..:em Action

(See Figure 1-13.)

1. Place end of access/return line in appropriate biohazard disposal container.
2. Press UNLOCK COVER key.
3. Slide centrifuge cover back.
4. Lower centrifuge door.
5. Remove three-lumen tubing from exit slot on right side of the system.
6. Remove collar from upper collar holder.
7. Remove upper bearing from upper bearing holder.
8. Remove lower bearing from lower bearing holder.
9. Push filler latching pin toward center of centrifuge and raise filler latch.
10. Pull tubes from slots in filler.
11. Pull channel from filler.
12. Open hinged cover on centrifuge collar holder and remove collar.
13. Raise channel above filler.
14. Fold channel in half and pull through loading port.
15. Discard channel in appropriate biohazard disposal container. (Channel will still be connected to tubing.)
16. Close centrifuge door and cover.

Operator Action	System Action

17. Remove lines from the following:

- Collect and plasma valves
- Return pressure sensor
- Waste divert valve
- RBC line valve
- Return and inlet air detectors
- Centrifuge pressure sensor
- Access pressure sensor
- Return line valve
- Anticoagulant level detector

18. Press CONTINUE key to unload pumps.

Unloading pumps.
Unload

All Pumps	-- 48 ml/min
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Time	-- 7 seconds

19. Remove lines from cartridge clamps (press clamps up to release pump cartridges).

20. Remove access/return needle and needle in saline container from tubing set and place them in appropriate needle disposal container.

21. Remove fluid containers and waste bag from the Spectra system. Remove single-needle bag from Return Flow Controller. Place fluid containers, waste bag, and single-needle bag in appropriate biohazard disposal container along with tubing.

COBE Spectra (Revision __).
Press CONTINUE to load tubing set.

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7-RBCX Operation

SECTION 7 - RBCX OPERATION

This procedure is intended for use when a RBCX blood tubing set is used to remove red blood cells from a patient requiring red blood cell exchange or erythrocytapheresis.

REQUIRED EQUIPMENT AND SUPPLIES

- COBE Spectra™ Apheresis System
- Single-stage channel filler
- RBCX flow path overlay
- Disposable RBCX blood tubing set (Catalog Number 777007-000)
- Anticoagulant (ACD-A – each 100 ml contains: 2.2 g sodium citrate hydrous, 730 mg citric acid anhydrous, and 2.45 g dextrose hydrous)
- 0.9% sodium chloride for injection (1000 ml). When only single-port saline containers are available and/or hypersensitivity reactions associated with ethylene oxide sterilization must be avoided, see **HOW TO USE AN ALTERNATIVE SINGLE-PASS PRIME PROCEDURE** in SECTION 10 – HELPFUL HINTS.
- Replacement fluids prescribed by physician. Typically –
  - Leukocyte-poor packed red blood cells for patients with sickle cell anemia or thalassemia
  - Normal saline or albumin for patients with polycythemia or hemochromatosis
- Microaggregate filters for selected replacement fluids
- Needles
- Forceps or hemostats

NOTE

During RBCX procedures, target values are invalid for the AC VOLUME, INLET VOLUME, and PLASMA VOLUME keys. Target time cannot be changed using the TIME MIN key. However, target time can be changed by changing the collect/replace volume using the COLLECT/REPLACE VOLUME key.

The values displayed on the AC status screen are also invalid during RBCX procedures.

Operator Action	System Action

Check System

1. Plug in Spectra Apheresis System.

2. Turn power switch ON.

The Spectra system will go through a short self-check to ensure that the various power supplies are operating at the correct voltage.

> Power up tests in progress.

> COBE Spectra (Program Revision __).
> Press CONTINUE to load tubing set.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- *Load Position
Plasma/RBC Valve	-- *Load Position
Collect Valve	-- *Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

*Refer to Appendix A for an explanation of valve positions.

3. Verify the following:

   - Yellow warning LED is illuminated.
   - "COBE Spectra (Revision __)" is displayed.
   - PAUSE LED is flashing.
   - Cartridge clamps are in load position.

Install Filler

1. Press UNLOCK COVER key.

2. Slide centrifuge cover back.

3. Lower centrifuge door.

4. Rotate centrifuge so centrifuge loading port (with alignment dot) is facing the front. (See Figure 7-1.)

5. If a dual-stage channel filler is in place, remove it as follows:

   - Push filler latching pin (No. 5 in Figure 1-13) toward center of centrifuge and raise filler latch (No. 6 in Figure 1-13).

Operator Action	System Action
• Push filler locking pin (No. 4 in Figure 1-13) toward center of centrifuge and raise filler.	
6. Position single-stage channel filler so dots on centrifuge and filler are aligned. (See Figure 7-1.)	

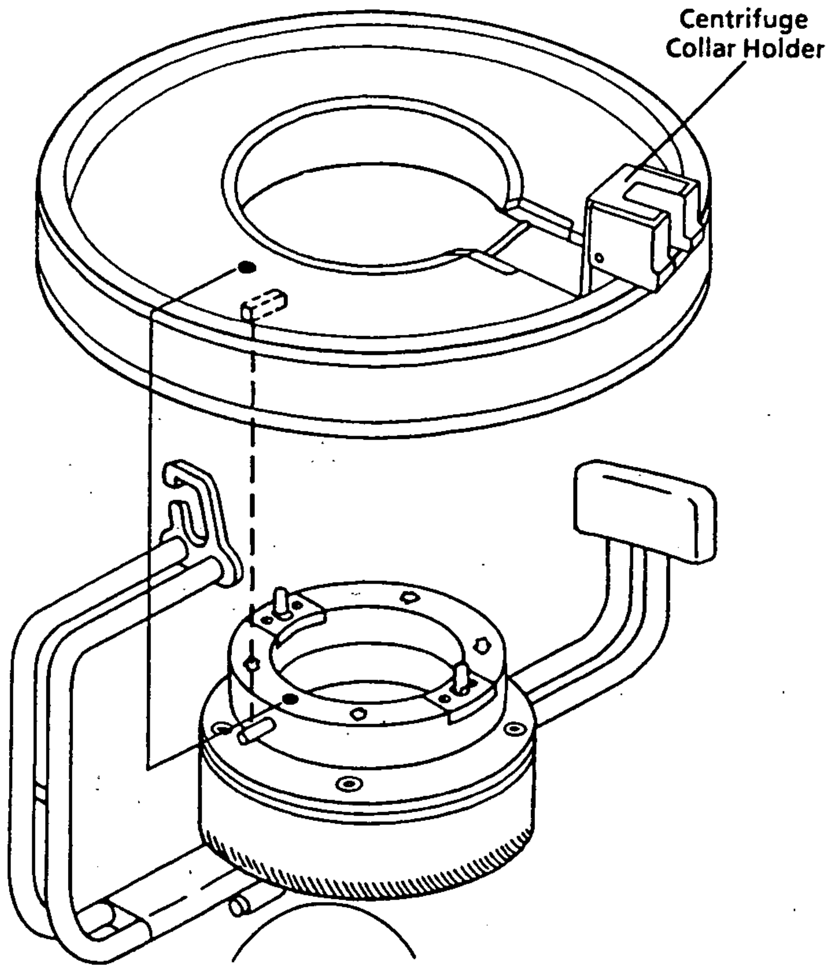


Figure 7-1. Correct Filler/Centrifuge Alignment

7. Place filler over centrifuge assembly, and press down until filler locking pin is securely in place.
8. Lower filler latch.
9. Lift up on filler to ensure it is securely in place.
10. Close centrifuge door and cover.
11. Install RBCX flow path overlay on front panel.

Operator Action	System Action

Place Tubing on Front Panel

(See Figure 1-14.)

1. Swing control panel to the side.
2. Peel back cover on disposables package.
3. Place disposables set package on centrifuge cover.
4. Package should be held securely by placing it underneath packaging hook on front panel.
5. Remove inlet line coil and remove white paper tapes. (See Figure 7-2.)

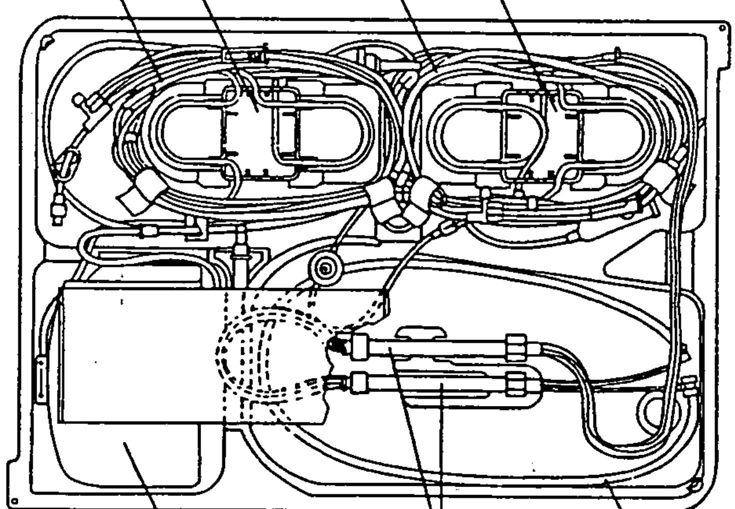


Figure 7-2. Packaged Tubing Set

a. Hang patient connection on hook on left side of IV pole. (For identification purposes, the three lines attached to this connection are taped together with red tape until they reach the front panel.)

b. Place access saline line (green-striped) over top of the system.

Operator Action	System Action
6. Remove return line coil and remove white paper tapes. (See Figure 7-2.)	
a. Hang patient connection on hook on left side of IV pole. (For identification purposes, the two lines attached to this connection are taped together with blue tape until they reach the front panel.)	
b. Place return saline line over the top of the system.	
7. Hang RBC 4-liter waste bag on two side-by-side hooks on IV pole (to far right). Hang prime-solution waste bag on a center hook.	
8. Clamp accessory "Y" line on RBC line (right line in No. 15 in Figure 1-10).	
9. Remove return pump cartridge and snap it between red blood cell pump and collect/replace pumps. (COBE label on cartridge should be facing up.)	
10. Remove access pump cartridge and snap it into cartridge clamp between AC and inlet pumps. (COBE label on cartridge should be facing up.)	
11. Place AC line over top of the system.	
12. Ensure all tubing is clear of pumps and untangled.	
13. Press CONTINUE key to load tubing into pump housings.	Cartridge clamps are retracted and tubing headers are threaded onto pump rotors.

Loading pumps.	Load

All Pumps	-- 48 ml/min
Centrifug:	-- Stopped
Waste Valve	-- Closed
Plasma/RBC Valve	-- Collect Position
Collect Valve	-- Collect Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Time	-- 10 seconds

Operator Action	System Action
14. Verify all four pumps are loaded.	After pumps are loaded, valves automatically open to load position.

Operator Action	System Action
15. Put lines in collect/replace and plasma valves.	
16. Lay replace solution spike assemblies over top of the system.	
17. Place sensor in return pressure sensor housing. Turn clockwise to lock in place.	
18. Place RBC/plasma line in RBC line valve. Ensure line is completely inserted in RBC detector.	
19. Position return and inlet air chambers in air detectors with air chamber filters located below air detector housings. Ensure waste divert lines are toward you.	
20. Put waste lines in waste valve assembly.	
21. Place line in centrifuge pressure sensor housing. Use a "flossing" action to ensure line is completely inserted in pressure sensor.	
22. Place sensor in access pressure sensor housing. Push downward and turn clockwise to lock in place.	
23. Position return line in return valve so line runs horizontally through center of valve.	
24. Release three-lumen tubing from package retainers.	

Operator Action

System Action

Install Channel in Centrifuge

(See Figure 1-13.)

1. Remove channel (Figure 7-2) from package.
2. Discard package.
3. Press UNLOCK COVER key.
4. Slide centrifuge cover back.
5. Lower centrifuge door.
6. Rotate centrifuge so loading port (No. 8 in Figure 1-13) is open to the front.
7. Ensure that centrifuge collar holder is resting on the outer rim of the filler. (See position of centrifuge collar holder in Figure 7-1.) If centrifuge collar holder is not resting on the outer rim of the filler, push filler latching pin (No. 5 in Figure 1-13) toward center of centrifuge, raise filler latch (No. 6 in Figure 1-13), and place it on the outer rim.
8. Extend centrifuge loop to full length to ensure three-lumen tubing is not twisted.
9. Fold channel in half.
10. Thread channel through lower loading port and pull it out from the top
11. Position channel in correct orientation above filler slots before placing centrifuge collar (Figure 7-3) into centrifuge collar holder (Figure 7-1).
12. Load centrifuge collar into centrifuge collar holder, closing cover over collar.
13. Lower filler latch into locked position.
14. Press channel into position, ensuring it is completely loaded in filler. Start at collection chamber and inlet chamber (Figure 7-3) and work around toward opposite side of channel.
15. Press tubes into appropriate slots in filler, ensuring all tubes are completely inserted.

Operator Action

System Action

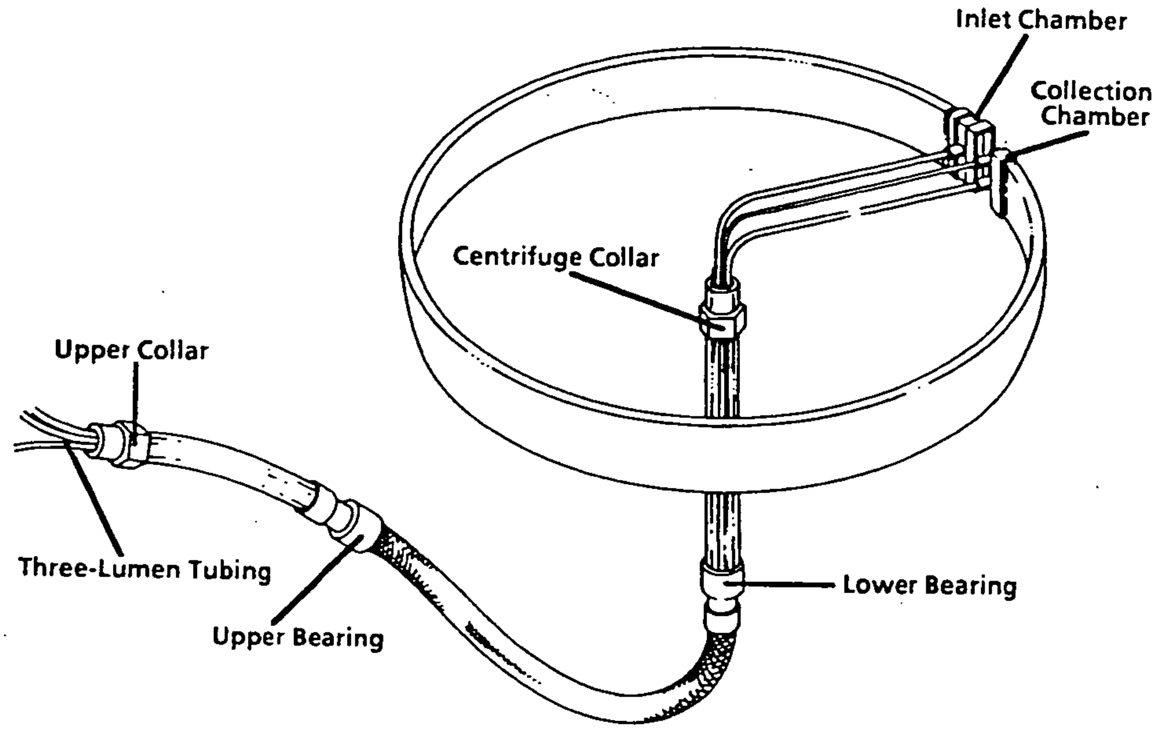
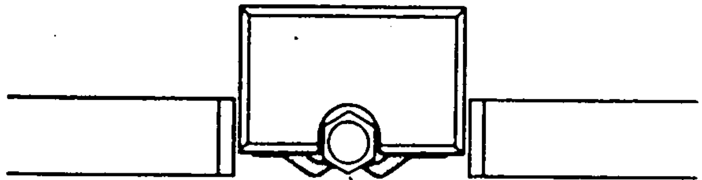


Figure 7-3. RBCX Single-Stage Channel

16. Pla.e lower bearing (Figure 7-3) in lower bearing holder (No. 10 in Figure 1-13).

17. Place upper bearing (Figure 7-3) in upper bearing holder (No. 11 in Figure 1-13).

18. Place upper collar (Figure 7-3) in upper collar holder (No. 12 in Figure 1-13). Ensure collar is held securely by visually checking that both black sides of holder are equally closed around collar and that an edge between two of the upper collar's six sides is facing out. Be sure that one of the upper collar's six sides is *not* facing out. See Figure 7-4.



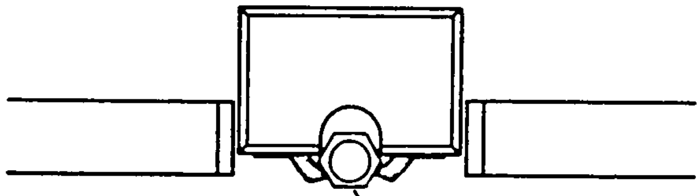


Figure 7-4. Upper Collar Placement

Operator Action	System Action
19. Use a "flossing" action to place three-lumen tubing in exit slot on right side of the system.	
20. Rotate centrifuge several times to ensure tubing does not twist and upper bearing remains in place.	

WARNING

Inspect all lines, especially those in the centrifuge and on the front panel, to ensure they are not kinked. Lines that are occluded, or partially occluded, may lead to fluid imbalance.

21. Close centrifuge door and cover.

RED BLOOD CELL EXCHANGE

Operator Action	System Action

Prime Tubing Set

(See Figure 1-10.)

When only single-port saline containers are available and/or hypersensitivity reactions associated with ethylene oxide sterilization must be avoided, see **HOW TO USE AN ALTERNATIVE SINGLE-PASS PRIME PROCEDURE** in SECTION 10 – HELPFUL HINTS.

Select set: 1 = Platelets or ELP,
2 = TPE, 3 = WBC, 4 = RBCX.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma/RBC Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

1. Press 4 key to select RBCX tubing set.

   If you make a mistake and enter the wrong set number:

   - Press the CHANGE MODE key.
   - Press 1 key to select Load Set.
   - Press the 4 key to select the RBCX blood tubing set and continue with Step 2.

Clamp access and return lines.
Close both saline lines. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma/RBC Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

2. Close white pinch clamps on access and return lines near luer connections. Close roller clamps on access and return saline lines.

Operator Action	System Action
3. Press CONTINUE key.	

> Connect RBCX tubing set to AC, saline, & replacement containers. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

CAUTION

Use aseptic technique throughout this procedure.

4. Connect AC line to anticoagulant container, and place AC line in AC level detector.

5. Connect inlet and return saline lines to same saline container. Using aseptic technique, clean injection port before inserting metal spike into it. Place plastic spike in spike port (after removing cover). Fill drip chambers 1/2 full.

CAUTION

Ensure lines are attached to correct fluids:

1. **AC line to anticoagulant container.**

2. **Access and return saline lines to normal saline container.**

Visually verify that fluid is flowing through the access, return, and AC spike and drip chambers.

6. Temporarily connect replace solution spikes to saline. (Microaggregate filters may be used for selected replacement fluids, for example, packed red blood cells. Ensure filters are primed *with saline* before use following manufacturer's instructions.) Fill drip chambers 1/2 full.

Operator Action | System Action

WARNING

Fluid imbalances can be caused by the following:

1. Using inadequately primed or clotted microaggregate filters used on replacement line.
2. Administering replacement fluids that are not at room temperature.
3. Using improperly vented replacement fluid containers.
4. Equipment malfunction.
5. Improper line clamping.
6. Using inadequately primed or clotted leukocyte-poor red blood cell filter on replacement line. Refer to filter manufacturer's guidelines to ensure that the filter can meet replacement fluid flow rates.

Monitor all solutions and procedures for correct fluid balance.

WARNING

Standard transfusion practices for cellular components should be followed.

7. Press CONTINUE key.

> Open access and return saline lines.
> Press CONTINUE to prime.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

Operator Action	System Action

WARNING

Once fluid has entered a tubing set, do not disturb sensors in pressure sensor housings because this will prevent transducers from monitoring pressures accurately. (See SECTION 12 - RECOVERY PROCEDURES for information on how to load pressure sensors with fluid in tubing set.)

8. Open access and return saline roller clamps.

9. Press CONTINUE key to prime tubing set.

If the Spectra system was not turned off after the last procedure, it will go through a short self-check before beginning Prime.

```
Power up tests in progress.
```

```
Priming anticoagulant line.
(RBCX Set)                                    Prime
```

AC Pump	-- 100 ml/min
Inlet Pump	-- Stopped
Plasma/RBC Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Inlet Divert Position
Plasma/RBC Valve	-- Collect Position
Collect Valve	-- Collect Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- 30 ml AC
Approximate Time	-- 18 second

10. Patient data can be entered before tubing set is primed, during Prime mode, or after priming is complete.

    a. To enter patient data before Prime mode, select set type (4 = RBCX) and press MENU ON/OFF key. Continue with Step 10d.

    b. To enter patient data during Prime mode, press MENU ON/OFF key. Continue with Step 10d.

    c. To enter patient data after priming is complete, continue with Step 11.

    d. Press 1 key to select "Data Entry." (Refer to following section, **Entering Patient Data**, for instructions on how to enter patient information.)

Operator Action | **System Action**

Priming inlet line and air chamber. (RBCX Set)	Prime

AC Pump	-- Stopped
Inlet Pump	-- 150 ml/min
Plasma/RBC Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Inlet Divert Position
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Volume	-- Fluid in Inlet Air Chamber Plus 25 ml
Approximate Time	-- 48 seconds

This step pumps saline through the access saline line, inlet line, and inlet air chamber. To prime the waste line, saline flows for a short time after fluid is detected in the inlet air chamber.

Testing sensors, valves, and pumps.	Prime

AC Pump	-- Stopped
Inlet Pump	-- Varies Flow
Plasma/RBC Pump	-- Varies Flow
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Varies Position
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Varies Position
Return Line Valve	-- Varies Position
Approximate Time	-- 51 seconds

Several valves change position as the Spectra system does a series of self-checks to ensure front panel components have been loaded correctly.

Priming centrifuge channel.	Prime

AC Pump	-- Stopped
Inlet Pump	-- 150 ml/min
Plasma/RBC Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 100 ml Inlet
Approximate Time	-- 40 seconds

Operator Action	System Action

Priming centrifuge channel. Prime

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma/RBC Pump	-- 150 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 250 ml Plasma
Approximate Time	-- 100 seconds

Priming centrifuge channel. Prime

AC Pump	-- Stopped
Inlet Pump	-- 120 ml/min
Plasma /RBC Pump	-- 120 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 82 ml Inlet
Approximate Time	-- 41 seconds

Priming centrifuge channel. Prime

AC Pump	-- Stopped
Inlet Pump	-- 120 ml/min
Plasma/RBC Pump	-- 120 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 200 ml Inlet
Approximate Time	-- 100 seconds

Operator Action	System Action

Testing sensors, valves, and pumps. Prime

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma/RBC Pump	-- Stopped
Collect Pump	-- Varies Flow Rate
Centrifuge	-- 1200 rpm
Waste Valve	-- Varies Position
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Time	-- 12 seconds

Priming return air chamber. Prime

AC Pump	-- 12.5 ml/min
Inlet Pump	-- 150 ml/min
Plasma/RBC Pump	-- Stopped
Collect Pump	-- 30 ml/min
Centrifuge	-- 800 rpm
Waste Valve	-- Return Divert Position
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- Fluid in Return Air Chamber Plus 25 ml
Approximate Time	-- 48 seconds

Priming return lines. Prime

AC Pump	-- 12.5 ml/min
Inlet Pump	-- 150 ml/min
Plasma/RBC Pump	-- 100 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC/Plasma Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 50 ml Inlet
Approximate Time	-- 20 seconds

Operator Action	System Action

Testing sensors, valves, and pumps.
Prime

AC Pump	-- Varies Flow Rate
Inlet Pump	-- Varies Flow Rate
Plasma/RBC Pump	-- Varies Flow Rate
Collect Pump	-- Varies Flow Rate
Centrifuge	-- Varies
Waste Valve	-- Varies Position
Plasma/RBC Valve	-- Varies Position
Collect Valve	-- Varies Position
RBC Line Valve	-- Varies Position
Return Line Valve	-- Varies Position
Approximate Time	-- 70 seconds

The various valves and pumps change position as the Spectra system does a series of self-checks.

Prime access and return connections.
Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

11. Open white pinch clamp near access luer connection. Allow saline to fill luer lock connection by gravity. Close white pinch clamp.

12. Open white pinch clamp near return luer connection. Allow saline to fill luer lock connection by gravity. Close white pinch clamp.

13. Press CONTINUE key.

Close access saline line. Clamp access line. Press CONTINUE to test AC ratio.

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

14. Use roller clamp to close green-striped access saline line, close white access pinch clamp, and press CONTINUE to test the AC ratio.

Operator Action	System Action
	Testing AC ratio. Prime

AC Pump	-- Varies Flow Rate
Inlet Pump	-- Varies Flow Rate
Plasma/RBC Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Time	-- 11 seconds

The AC and inlet pumps change flow rates as the system does a series of self-checks.

WARNING: Do not connect donor/patient before running Alarm Tests. CONTINUE.

15. Press CONTINUE key to clear this warning from screen.

Perform alarm tests (YES/NO)?

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Time	-- 9 seconds

16. Press YES key to run semiautomatic alarm tests. Refer to SECTION 9 – DIAGNOSTICS for **ALARM TESTS** procedure.

At this point the Spectra system provides an opportunity to verify that key alarm systems are fully operational. Alarm tests will check operation of access pressure sensor, return air detector, return pressure sensor, fluid leak detector, and centrifuge door and cover safety system.

17. Remove replace solution spikes from saline container.

18. Connect replace solution spikes to replacement fluid prescribed by physician, for example, leukocyte-poor washed, packed red blood cells for patients with sickle cell anemia or thalassemia and normal saline or albumin for patients with polycythemia or hemochromatosis.

Operator Action	System Action

NOTE

To meet transfusion standards, you may need to place a transfusion filter between the replacement solution spikes and the cellular replacement fluid. If a transfusion filter is used, ensure that it is properly primed prior to use.

Enter Patient Data

The Spectra system will customize red blood cell or erythrocytopheresis procedures by using patient data to calculate pump flow rates, centrifuge speed, remove/replace volumes, end hematocrit, fraction of defective cells remaining, and procedure time. All red blood cell exchange procedures have a default inlet:AC ratio of 13:1.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

```
Select sex:   1 = Male,  2 = Female.
   (ENTER = Male)
```

1. Enter patient sex:

   - Press 1 if male.
   - Press 2 if female.
   - Press ENTER for default (data in parentheses).

(English units - enter feet):

```
Enter height,
in feet:   {0}   , and/or inches:  0
```

(Range: 1 to 7 feet)

2. Enter patient height:

Feet and Inches	Inches	Centimeters
_ feet plus ENTER then _ inches plus ENTER	ENTER then _ inches plus ENTER	_ centimeters plus ENTER
Range: 1-7 ft	Range: 12-84 in.	Range: 30-220 cm

Operator Action	System Action
	(English units): **Enter weight, in pounds: {0}** (Range: 10 to 500 lbs)
3. Enter patient weight in pounds (or kilograms). Then press ENTER key.	
	Total blood volume = ________ ml. (_____ in, _____ lbs, Female). OK (YES/NO)? To confirm input, the Spectra system displays estimated total blood volume and patient data. Total blood volume is calculated from patient data entered into system. The second line of display reviews data input: height, weight, and sex.
4. Confirm patient data input: • Press NO one time = weight entry display. Press NO two times = height entry display. Press NO three times = sex entry display. • Press YES = next display: hematocrit entry.	
	Enter hematocrit (%): {41} (Range: 10% to 70%)
5. Enter patient hematocrit as a whole number. (Decimal not required.) Then press ENTER key.	The system will use default values of 45% for males and 41% for females.
	Enter average replacement fluid hematocrit (%): {80} (Range: 0% to 99%)
6. Either press ENTER key to accept the default value of 80% for the average hematocrit of the replacement red blood cells or change to a value between 0% and 99%. Then press ENTER key. To calculate the correct hematocrit, determine the average (by volume) of the hematocrits of all of the replacements red cell bags. Entering 0% will result in a red cell depletion.	

Operator Action | **System Action**

```
Enter end hematocrit (%):  {0}
```

(Range: 9% to 70%)

7. Change 0% to a value between 9% and 70% for the patient hematocrit desired at the end of the procedure. Press ENTER key.

   If the average replacement fluid hematocrit is 0% (signifying a red blood cell deplete), the end hematocrit must be less than the initial hematocrit.

```
Patient Hct = ___%,    End Hct = ___%,
Average replace Hct = ___%,   OK (YES/NO)?
```

To confirm input, the Spectra system displays all entered hematocrits.

8. Press ENTER/YES key to accept displayed hematocrits. If they are not acceptable, press CLEAR/NO KEY and the *patient hematocrit entry message* that precedes Step 5 above is redisplayed.

```
Enter fluid balance desired:
FB = {100} %
```

(Range: 75% to 150%)

9. Either press ENTER key to accept the default patient fluid balance of 100% or change fluid balance to a value between 75% and 150%. Then press ENTER key.

The Spectra control program defines RBCX fluid balance as combined infusion rates (replace flow plus AC flow) divided by RBC pump flow rate and multiplied by 100 as follows:

$$\textit{Percentage} = \frac{\textit{Replace Rate + AC Rate}}{\textit{RBC Pump Flow Rate}} \times 100$$

The Spectra algorithms' calculation of fluid balance does not include approximately 150 ml of volume removed from patient during waste divert and approximately 345 ml of saline returned to patient during rinseback.

Operator Action	System Action
	Rinseback volume is not considered in the calculation of predicted end hematocrit and fraction of original cells remaining.
	Calculate replacement fluid volume needed (YES/NO) ?
	If desired, Spectra algorithms will calculate the quantity of replacement fluid required to achieve a particular result.
10. a. Generally, press CLEAR/NO key if the RBCX data are being entered when you are ready to actually begin the RBCX procedure and, thus, you know the *actual* volume of the available replacement fluid. Continue with Step 11. OR b. Press ENTER/YES key if you want to calculate the amount of red blood cell replacement fluid to order a day or two before a RBCX procedure is to be performed. Continue with **RBCX Patient Data for Calculation of Required Replacement Fluid** section.	
	Enter total replacement fluid volume: { 0} ml. (Range: 100 to 9999 ml)
11. Enter value between 100 and 9999 ml for the total volume of replacement fluid available and press ENTER key.	
	Once this value is entered, the Spectra algorithms will calculate the process time required and the fraction of original cells (defective red blood cells) remaining at the end of the RBCX procedure (Fraction of Cells Remaining = FCR). If the results are valid, the message below will be displayed. If the results are not valid, the "Invalid Process Time" warning alarm will be generated. See this message in SECTION 11 - TROUBLESHOOTING.
	Replace = ___ml, FB = ___%, FCR = ____ %, End Hct = ___%, time = ___min. OK(YES/NO)?

CLI 121763

Operator Action

System Action

The Spectra control program uses patient data (entered above) and microprocessor alogrithms to calculate and show the following information on the RBCX results display:

- Red blood cell replacement volume (in milliliters) equals the value entered in Step 11 for the volume of total replacement fluids returned to the patient. Maximum volume replaced is 9,999 ml.
- Fluid balance (in %) is the ratio of the replaced/removed red blood cell flow rates. For the exact formula used to calculate, see Step 9 above.
- Calculated fraction of initial red blood cells (defective hemoglobin) remaining.
- Patient hematocrit desired at end of procedure. (Entered in Step 7.)
- Calculated process time.

12. Approve red blood cell exchange results:

- Press ENTER/YES = exit patient data entry displays and continue to **Connect Patient** section
- Press CLEAR/NO = next display: *change RBCX settings message*

Change: 1 = Fluid Balance, 2 = Replacement cell volume, 3 = End Hct.

IMPORTANT: Changing one value affects other values. For instance:

Changed Value	Affected Value
Fluid Balance	Fraction of Cells Remaining Process Time
Replacement Cell Volume	Fraction of Cells Remaining Process Time
End Hematocrit	Fraction of Cells Remaining Process Time

Operator Action | **System Action**

13. Select RBCX value to be changed:

- Press 1 = braces around fluid balance
- Press 2 = braces around replacement cell volume
- Press 3 = braces around end hematocrit
- Press CLEAR/NO = redisplays *change RBCX settings message* (follows Step 12 above)

Replace = ___ml, FB = ___%, FCR = ____ %, End Hct = ___%, time = ___min.

14. Using arrow keys, change selected value. The up arrow key increases the value, and the down arrow key decreases it. Affected value(s) will also be changed. When satisfied that changed and affected values are appropriate, press ENTER key to return to *RBCX results message* (follows Step 11 above). Pressing CLEAR key redisplays the *change RBCX settings message* (follows Step 12 above).

    When changing selected RBCX values, the following value ranges are allowed for changed values:

Changed Value	Allowed Range
Fluid Balance	75%-150%
Replacement Cell Volume	100-9999 ml
End Hematocrit	10%-70%

15. Continue with **Connect Patient** steps.

RBCX Patient Data Entry for Calculation of Required Replacement Volume

Enter desired Fraction of Red Cells Remaining: FCR = { 0} %.

(Range: 1% to 100%)

NOTE

This screen will be skipped if zero was entered as the average hematocrit of the red blood cell replacement fluid.

1. Enter value between 1% and 100% for the desired fraction of patient's red blood cells remaining at the end of a RBCX procedure.

Operator Action

System Action

Once this value is entered, the Spectra system will calculate the volume of replacement red blood cells needed. If the result is not valid, the "Invalid Replacement Fluid Volume" warning alarm will be displayed. See this message in SECTION 11 - TROUBLESHOOTING. If the result is valid, the following entry message will appear.

Replace = ___ml, FB = ___%, FCR = ___ %, End Hct = ___%, time = ___min. OK(YES/NO)?

2. Approve red blood cells exchange results:

- Press ENTER/YES = exit **Calculation of Required Replacement Volume** and continue with *RBCX replacement volume data entry message* (follows Step 10 in **Enter Patient Data** section)
- Press CLEAR/NO = next display: *change RBCX replacement volume settings message*

Change: 1 = Fluid Balance, 2 = FCR, 3 = End Hct.

IMPORTANT: Changing one value affects other values. For instance:

Changed Value	Affected Value
Fluid Balance	Replacement Volume
Fraction of Cells Remaining	Decreased FCR = Increased Replacement Volume and Increased Process Time
End Hematocrit	Replacement Volume Process Time

3. Select RBCX value to be changed:

Operator Action	System Action
• Press 1 = braces around fluid balance • Press 2 = braces around fraction of cells remaining • Press 3 = braces around end hematocrit • Press CLEAR key = redisplays *RBCX replacement volume calculation results message* (precedes Step 2 this section)	Replace = ___ml, FB = ___%, FCR = ___ %, End Hct = ___%, time = ___min.

4. Using arrow keys, change selected value. The up arrow key increases the value, and the down arrow key decreases it. Affected value(s) will also be changed. When satisfied that changed and affected values are appropriate, press ENTER key to return to the *RBCX replacement volume calculation results message* (precedes Step 2 this section).

   Pressing the CLEAR key redisplays the change RBCX replacement volume settings message (follows Step 2 above).

   When changing selected RBCX values, the following value ranges are allowed for changed values:

Changed Value	Allowed Range
Fluid Balance	75%-150%
Fraction of Cells Remaining	1%-99%
End Hematocrit	10%-70%

NOTE

Changing the replacement volume and end hematocrit after the beginning of the Run mode or ending the run prematurely invalidate the displayed end of run FCR as well as the FCR that was predicted at the beginning of the procedure. Changing the inlet flow rate after the beginning of the Run mode does not affect the accuracy of the initial predicted FCR but does invalidate the displayed end of run FCR.

Connect Patient

WARNING

Before connecting patient, check access and return lines for air. If air is present in these lines, do not connect patient. Remove air before starting procedure.

Operator Action	System Action
	Connect access and return lines. Close access saline. Press CONTINUE to Run.

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Load Position
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

1. Perform venipuncture at access and return needle sites.
2. Open white pinch clamps on access and return lines.
3. Leave a saline drip on the return line to keep return needle from clotting.
4. Close roller clamp on green-striped access saline line.

Start Run Mode

WARNING

Monitor the patient closely for reactions any time biologically derived replacement fluids are being used.

NOTE

To understand RBCX anticoagulation, note that the calculation of predictive RBCX results is complicated. Consequently, anticoagulation (AC) infusion control is calculated somewhat differently for RBCX procedures. The Spectra system will use a standard AC pump flow rate of 0.9 ml/min/liter TBV, ignoring the configured AC infusion rate. Just as in other procedures, you can change the AC infusion rate for RBCX procedures by changing the inlet flow rate.

NOTE

Following the Divert Prime mode, changes to replacement fluid hematocrit are invalid. This value is an average of the hematocrits of all replacement fluids used throughout the run and should be entered as such during Patient Data entry. See **Enter Patient Data** subsection of this section.

1. Press CONTINUE key to start the system in Run mode.

All pumps will start and centrifuge speed will increase based on parameters preset by patient data and Spectra algorithms.

Operator Action	System Action

AC	Inlet	Plasma	Collect Replace	Inlet : AC Ratio	Spin RPM
_._	___._	___._	___._	___._	_____

Diverting prime saline.

AC Pump	-- ___._ ml/min
Inlet Pump	-- ___._ ml/min
Plasma/RBC Pump	-- ___._ ml/min
Collect Pump	-- ___._ ml/min
Ratio	-- _ : 1
Centrifuge	-- ______ rpm
Waste Valve	-- Return Divert Position
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

NOTE

It is normal that a small amount of red cells may be diverted to the waste bag when prime saline is diverted.

2a. If you want to divert the prime saline to the waste bag, continue with Step 3.

OR

2b. If you do not want to divert the prime saline to the waste bag and, instead, want to return it to the patient, follow these steps:

- Press the CHANGE MODE key.
- Press 3 key to select Run.
- Close the roller clamp on the return saline line. (The system will not prompt you to do this.)
- Press CONTINUE key.
- Continue with Step 4, but **do not** press CLEAR.

Operator Action	System Action
	(display)

Operator Action / **System Action**

AC	Inlet	Plasma	Collect Replace	Inlet : AC Ratio	Spin RPM
__.__	____.__	____.__	____.__	____.__	_____

Close return saline. Press CLEAR.

AC Pump	-- ____.__ ml/min
Inlet Pump	-- ____.__ ml/min
Plasma/RBC Pump	-- ____.__ ml/min
Collect Pump	-- ____.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- _______ rpm
Waste Valve	-- Closed
Plasma/RBC Valve	-- Variable Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Audio: Operator-attention alarm sounds.

3. Use roller clamp to close return saline line because blood flow is being returned to patient.

4. Press CLEAR key.

The Spectra system automatically establishes red cell/plasma interface and starts removing red cells. The rate at which replacement fluid is returned to patient will be determined by previously selected fluid balance.

The system displays pump flow rates, anticoagulant ratio, centrifuge rpm, accumulated volumes processed, and procedure type.

AC	Inlet	Plasma	Collect Replace	Inlet : AC Ratio	Spin RPM
__.__	____.__	____.__	____.__	____.__	_____
____	______	______	______	______	RBCX
AC	Inlet	Plasma	Collect Replace	Time Min	Procedure

AC Pump	-- ____.__ ml/min
Inlet Pump	-- ____.__ ml/min
Plasma/RBC Pump	-- ____.__ ml/min
Collect Pump	-- ____.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- _______ rpm
Waste Valve	-- Closed
Plasma/RBC Valve	-- Variable Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

5. During procedure, red cell/plasma interface should be monitored every 30 minutes to ensure red cells are not accumulating in channel. (See Figure 7-5.)

Operator Action

System Action

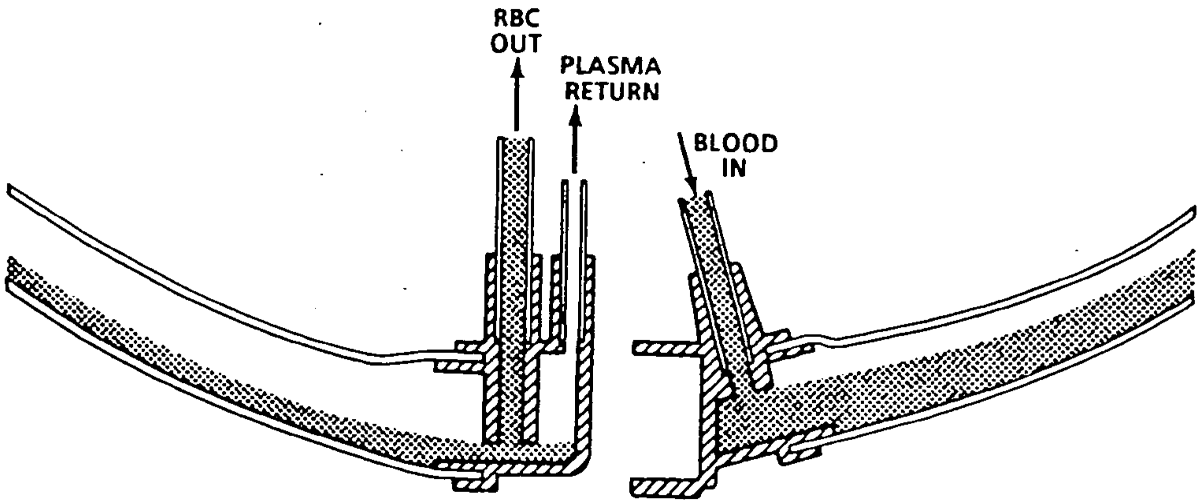


Figure 7-5. Correct Red Cell/Plasma Interface

6. If red cells are accumulating in channel (see Figure 7-6), perform procedure for **RED CELL ACCUMULATION IN RBCX CHANNEL** in SECTION 12 - RECOVERY PROCEDURES.

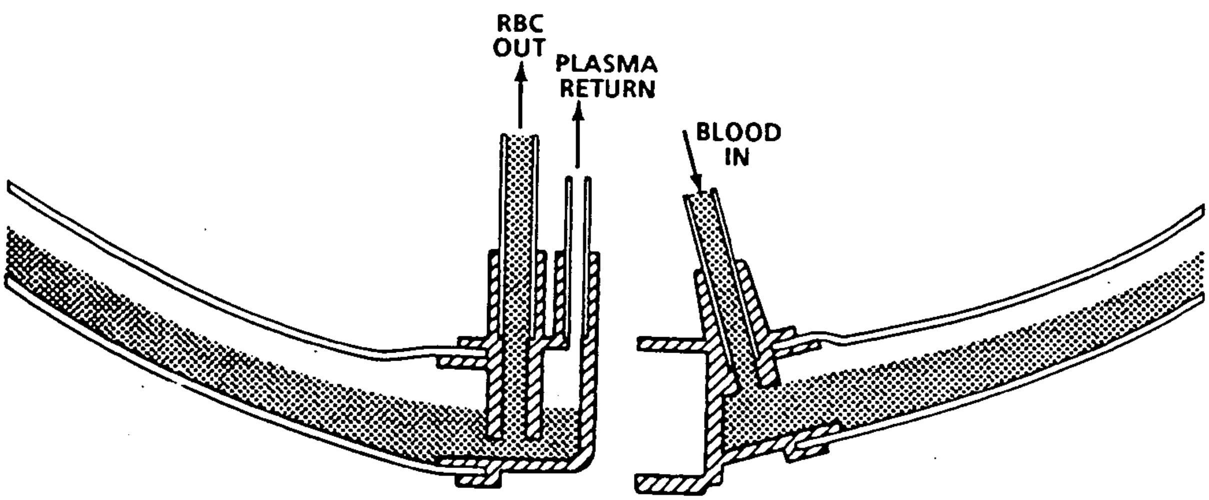


Figure 7-6. Red Cell Accumulation in RBCX Channel

Run mode continues until target values are reached. There are audio and visual warnings when Run mode is complete. The values that have exceeded their limits will be flashing.

Operator Action	System Action

NOTE

If the desired fluid balance is 100%, the plasma/RBC and replace pump flow rates will vary during the run in the Automatic mode.

If the desired fluid balance is not 100%, all pump flow rates will vary during the Automatic mode.

```
End of Run:  1 = Rinseback, 2 = Continue Run.
                                          RBCX
____   ____   ____   ____   ____
```

AC	Inlet	Plasma	Collect / Replace	Time Min	Procedure

AC Pump -- ___.__ ml/min
Inlet Pump -- ___.__ ml/min
Plasma/RBC Pump -- ___.__ ml/min
Collect Pump -- ___.__ ml/min
Ratio -- __ : 1
Centrifuge -- ______ rpm
Waste Valve -- Closed
Plasma/RBC Valve -- Variable Position
Collect Valve -- Load Position
RBC Line Valve -- Open
Return Line Valve -- Open

7. Press 2 key to continue Run mode. (To start Rinseback mode, press 1 key and skip to **Start Rinseback Mode** section.)

If no selection is made, a shutdown alarm will occur after 10 minutes and the pumps will stop.

```
Increase flashing target limits.
                                          Target
____   ____   ____   ____   ____
```

AC	Inlet	Plasma	Collect / Replace	Time Min	Procedure

All Pumps -- ___.__ ml/min
Ratio -- __ : 1
Centrifuge -- ______ rpm
Waste Valve -- Closed
Plasma/RBC Valve -- Variable Position
Collect Valve -- Load Position
RBC Line Valve -- Open
Return Line Valve -- Open

8. Select flashing target value on bottom row of display.

Inlet volume processed is the only value that flashes.

9. To increase inlet volume, press appropriate key.

10. Enter new target value on numeric keypad. Then press ENTER.

Run mode continues until target values are reached. There are audio and visual warnings when Run mode is complete.

Operator Action	System Action

End of Run: 1 = Rinseback, 2 = Continue Run.
____ _____ _____ _____ _____ RBCX

AC	Inlet	Plasma	Collect Replace	Time Min	Procedure

AC Pump -- ___._ ml/min
Inlet Pump -- ___._ ml/min
Plasma/RBC Pump -- ___._ ml/min
Collect Pump -- ___._ ml/min
Ratio -- _ : 1
Centrifuge -- ______ rpm
Waste Valve -- Closed
Plasma/RBC Valve -- Variable Position
Collect Valve -- Load Position
RBC Line Valve -- Open
Return Line Valve -- Open

Skip Rinseback

If you do want to run Rinseback, skip the steps in this section and continue with the **Start Rinseback Mode** section.

If you do not want to run Rinseback, skip the steps in the **Start Rinseback Mode** section and follow the steps below:

1. Disconnect the patient following Step 1 in the **Disconnect Patient** section.

2. Press CHANGE MODE key.

1 = Load Set, 2 = Prime, 3 = Run, 4 = Rinseback,
5 = Unload Set, 6 = Diagnostics.

3. Press 5 to select Unload Set.

Final values. Press CONTINUE to unload.
____ _____ _____ _____ _____ _____

AC	Inlet	Plasma	Collect Replace	Time Min	Procedure

All Pumps -- Stopped
Centrifuge -- Stopped
Waste Valve -- Load Position
Plasma/RBC Valve -- Load Position
Collect Valve -- Load Position
RBC Line Valve -- Open
Return Line Valve -- Open

4. Record on patient records the final volumes processed during the procedure.

Operator Action	System Action
5. Continue with **REMOVING RBCX DISPOSABLES** section.	

Start Rinseback Mode

Operator Action	System Action
1. Press 1 key to start Rinseback mode.	If no selection is made, a shutdown alarm will occur after 10 minutes.

> Clamp & disconnect access. Open access saline. Press CONTINUE to Rinseback.

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma /RBC Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- _______ rpm
Waste Valve	-- Closed
Plasma/RBC Valve	-- Variable Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

2. Close white pinch clamp on access line. Open roller clamp on green-striped access saline line to allow saline to enter system.

3. Press CONTINUE key to start Rinseback.

4. Disconnect access needle and place in appropriate needle disposal container.

> Clamp and disconnect collection bags. Press CLEAR.

AC Pump	-- Stopped
Inlet Pump	-- 50.0.ml/min
Plasma/RBC Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

NOTE

If the inlet flow was higher than 50 ml/min during the Run mode, the inlet pump will run at the higher rate.

Operator Action	System Action
5. **IMPORTANT**: Close slide clamp(s) on line(s) leading to replacement fluid bag(s).	
6. Press CLEAR to continue Rinseback.	

Rinseback: Returning RBCs.
Rinse.

AC Pump	-- Stopped
Inlet Pump	-- 50.0.ml/min
Plasma/RBC Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 120 ml Inlet
Approximate Time	-- 144 seconds

NOTE

If the inlet flow was higher than 50 ml/min during the Run mode, the inlet pump will run at the higher rate.

Plasma line is only flow back to patient during this step.

Rinseback: Recirculating.
Rinse.

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma/RBC Pump	-- 150.0 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Recirculate Position
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Volume	-- 300 ml through Plasma/RBC pump
Approximate Time	-- 120 seconds

The Spectra system closes return line valve and flushes red cells off channel wall by recirculating saline through channel at high speed.

Operator Action	System Action

NOTE

No flow to or from patient during this step.

```
Rinseback:  Evacuating channel.
                                  Rinse.
```

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma/RBC Pump	-- 40.0 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 150 ml through Plasma/RBC pump
Approximate Time	-- 225 seconds

The system opens return line valve so free red cells can be returned to patient. Channel is collapsed to reduce extracorporeal blood volume.

```
Rinseback:  Rinsing channel.
                                  Rinse.
```

AC Pump	-- Stopped
Inlet Pump	-- 40.0 ml/min
Plasma/RBC Pump	-- 40.0 ml/min
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 75 ml Inlet
Approximate Time	-- 90 seconds

NOTE

If the inlet flow was higher than 40 ml/min during the Run mode, the inlet pump will run at the higher rate.

The system allows additional saline to enter channel to flush final red cells back to patient.

Operator Action	System Action

Disconnect Patient

Rinseback completed. Disconnect return line. Close fluids. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma/RBC Valve	-- Return Position
Collect Valve	-- Load Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed

1. When Rinseback mode is completed, close white pinch clamp on return line. Disconnect return needle. Close roller clamp on green-striped access saline line. Close slide clamp on replacement fluid line.

2. Press CONTINUE key.

Final values. Press CONTINUE to unload.

AC	Inlet	Plasma	Collect Replace	Time Min	Procedure
___	___	___	___	___	___

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma/RBC Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

3. Record on patient records the final volumes processed during procedure.

REMOVING RBCX DISPOSABLES

Operator Action	System Action
(See Figure 1-13.)	
1. Place ends of patient access and return lines in appropriate biohazard disposal container.	
2. Press UNLOCK COVER key.	
3. Slide centrifuge cover back.	
4. Lower centrifuge door.	
5. Remove three-lumen tubing from exit slot on right side of the system.	
6. Remove collar from upper collar holder.	
7. Remove upper bearing from upper bearing holder.	
8. Remove lower bearing from lower bearing holder.	
9. Push filler latching pin toward center of centrifuge and raise filler latch.	
10. Pull tubes from slots in filler.	
11. Pull channel from filler.	
12. Open hinged cover on centrifuge collar holder and remove collar.	
13. Raise channel above filler.	
14. Fold channel in half and pull through loading port.	
15. Discard channel in appropriate biohazard disposal container. (Channel will still be connected to tubing.)	
16. Close centrifuge door and cover.	

Operator Action	System Action
17. Remove lines from the following: • Collect and plasma/RBC valves • Return pressure sensor • Waste divert valve • RBC line valve • Return and inlet air detectors • Centrifuge pressure sensor • Access pressure sensor • Return line valve • Anticoagulant level detector	
18. Press CONTINUE key to unload pumps.	Unloading pumps. Unload All Pumps -- 48 ml/min Centrifuge -- Stopped Waste Valve -- Load Position Plasma/RBC Valve -- Load Position Collect Valve -- Load Position RBC Line Valve -- Open Return Line Valve -- Open Approximate Time -- 7 seconds
19. Remove lines from cartridge clamps (press clamps up to release pump cartridges).	
20. Remove return needle and needle in saline container from tubing set and place them in appropriate needle disposal container.	
21. Remove fluid containers and waste bag from Spectra system, and place in appropriate biohazard disposal container along with tubing.	COBE Spectra (Revision __). Press CONTINUE to load tubing set.

SECTION 8 - WBC OPERATION

This procedure is intended for use when an WBC blood tubing set is used to remove mononuclear cells (MNC) or granulocytes [polymorphonuclear cells (PMN)] from a human subject. The Spectra system requires operator attention during these procedures. All steps apply to both MNC and PMN removal procedures except where the steps are specifically labeled as applying to only a MNC or PMN procedure.

Granulocyte (PMN) concentrates for homologous transfusion are not a biological product licensed by the U.S. Food and Drug Administration. COBE makes no claims for the efficacy of the product collected by this procedure.

REQUIRED EQUIPMENT AND SUPPLIES

MNC and PMN PROCEDURES

- COBE Spectra™ Apheresis System
- Single-stage channel filler
- Collect flow path overlay
- Disposable WBC blood tubing set (Catalog Number 777006-000)
- 0.9% sodium chloride for injection (1000 ml). When only single-port saline containers are available and/or hypersensitivity reactions associated with ethylene oxide sterilization must be avoided, see **HOW TO USE AN ALTERNATIVE SINGLE-PASS PRIME PROCEDURE** in SECTION 10 – HELPFUL HINTS.
- Needles
- Forceps or hemostats

MNC PROCEDURES ONLY

- Anticoagulant (ACD-A – each 100 ml contains: 2.2 g sodium citrate hydrous, 730 mg citric acid anhydrous, and 2.45 g dextrose hydrous)

PMN PROCEDURES ONLY

- Hydroxyethyl starch (HES) – combine each 500-ml unit of HES with 30-40 ml of sodium citrate concentrate. HES is a sedimenting agent that enhances the separation of granulocytes from red blood cells during centrifugation.

NOTE

If a sedimenting agent is not used, you should follow the MNC procedure steps.

- Sodium citrate concentrate (46.7% trisodium citrate)

Operator Action	System Action

Check System

NOTE

For PMN procedures, the attending physician may prescribe that subjects receive steroids prior to the procedure to stimulate the release of granulocytes into the peripheral circulation.

1. Plug in Spectra Apheresis System.
2. Turn power switch ON.

The system will go through a short self-check to ensure that the various power supplies are operating at the correct voltage.

> Power up tests in progress.

> COBE Spectra (Program Revision _).
> Press CONTINUE to load tubing set.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- *Load Position
Plasma Valve	-- *Load Position
Collect Valve	-- *Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

*Refer to Appendix for an explanation of valve positions.

3. Verify the following:
   - Yellow warning LED is illuminated.
   - "COBE Spectra (Revision _)" is displayed.
   - PAUSE LED is flashing.
   - Cartridge clamps are in load position.

Install Filler

1. Press UNLOCK COVER key.
2. Slide centrifuge cover back.
3. Lower centrifuge door.
4. Rotate centrifuge so centrifuge loading port (with alignment dot) is facing the front. (See Figure 8-1.)

Operator Action	System Action
5. If a dual-stage channel filler is in place, remove it as follows:	
• Push filler latching pin (No. 5 in Figure 1-13) toward center of centrifuge and raise filler latch (No. 6 in Figure 1-13).	
• Push filler locking pin (No. 4 in Figure 1-13) toward center of centrifuge and raise filler.	
6. Position single-stage channel filler so dots on centrifuge and filler are aligned. (See Figure 8-1.)	

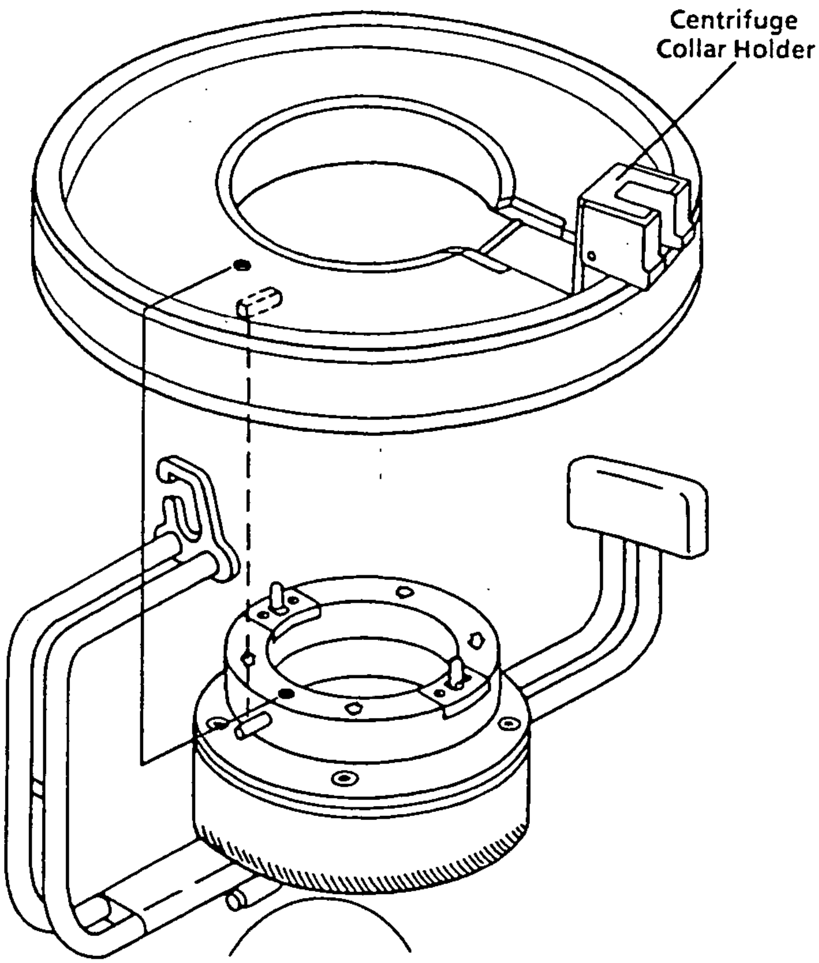


Figure 8-1. Correct Filler/Centrifuge Alignment

7. Place filler over centrifuge assembly, and press down until filler locking pin is securely in place.

Operator Action	System Action
8. Lower filler latch.	
9. Lift up on filler to ensure it is securely in place.	
10. Close centrifuge door and cover.	
11. Install collect flow path overlay on front panel.	

SETTING UP WBC DISPOSABLES

Operator Action	System Action

Place Tubing on Front Panel

(See Figure 1-14.)

NOTE

Collect line may be sampled to measure hematocrit, cell type, and cell count of removal. (To make a sampling site, using aseptic technique, disconnect collect bag from tubing set, connect stopcock to luer, and reattach collect bag. This should be done prior to priming the set.)

1. Swing control panel to the side.
2. Peel back cover on disposables package.
3. Place disposables set package on centrifuge cover.
4. Package should be held securely by placing it underneath packaging hook on front panel.
5. Remove inlet line coil and remove white paper tapes. (See Figure 8-2.)

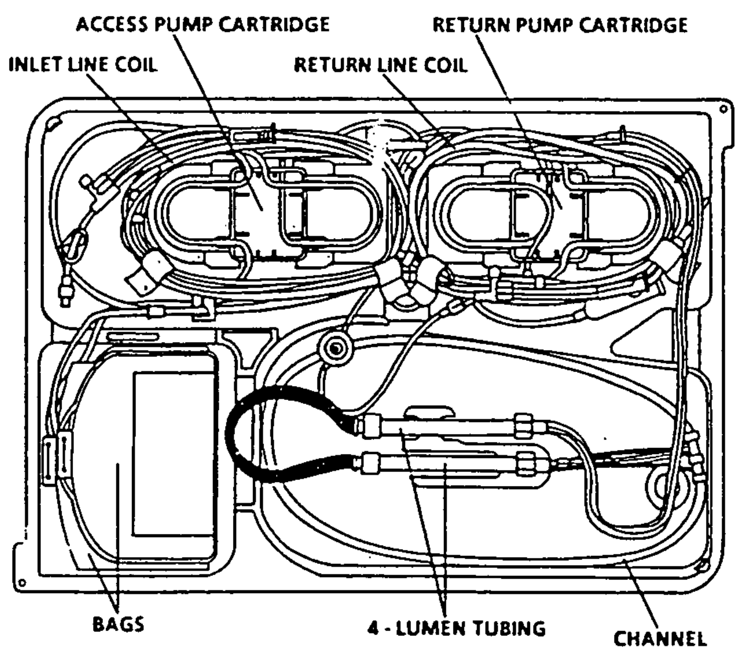


Figure 8-2. Packaged Tubing Set

Operator Action	System Action
a. Hang human subject connection on hook on left side of IV pole. (For identification purposes, the three lines attached to this connection are taped together with red tape until they reach the front panel.)	
b. Place access saline line (green striped) over top of the system.	
6. Remove return line coil and remove white paper tapes. (See Figure 8-2.)	
a. Hang human subject connection on hook on left side of IV pole. (For identification purposes, the two lines attached to this connection are taped together with blue tape until they reach the front panel.)	
b. Place return saline line over top of the system.	
7. Hang bags on one hook on the IV pole.	
8. Remove return pump cartridge and snap it into the cartridge clamp between the plasma and collect/replace pumps. (COBE label on cartridge should be facing up.)	
9. Remove access pump cartridge and snap it into the cartridge clamp between the AC and inlet pumps. (COBE label on cartridge should be facing up.)	
10. Place AC line over top of the system.	
11. Ensure all tubing is clear of pumps and untangled.	
12. Press CONTINUE key to load tubing into pump housings.	Cartridge clamps are retracted and tubing headers are threaded onto pump rotors.

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Operator Action	System Action
	Loading pumps. Load
	All Pumps -- 48 ml/min Centrifuge -- Stopped Waste Valve -- Closed Plasma Valve -- Collect Position Collect Valve -- Collect Position RBC Line Valve -- Closed Return Line Valve -- Closed Approximate Time -- 10 seconds
13. Verify all four pumps are loaded.	After pumps are loaded, valves automatically open to load position.

14. Put lines in collect/replace and plasma valves.

15. Place sensor in return pressure sensor housing. Turn clockwise to lock in place.

16. Place RBC line in RBC valve. Ensure line is completely inserted in RBC detector.

17. Position return and inlet air chambers in air detectors with air chamber filters located below air detector housings. Ensure waste divert lines are toward you.

18. Put waste lines in waste valve assembly.

19. Place line in centrifuge pressure sensor housing. Use a "flossing" action to ensure line is completely inserted in pressure sensor.

20. Place sensor in access pressure sensor housing. Push downward and turn clockwise to lock in place.

21. Position return line in return valve so line runs horizontally through center of valve.

22. Release four-lumen tubing from package retainers.

Install Channel in Centrifuge

(See Figure 1-13.)

1. Remove channel (Figure 8-2) from package.

2. Discard package.

3. Press UNLOCK COVER key.

Operator Action	System Action
4. Slide centrifuge cover back.	
5. Lower centrifuge door.	
6. Rotate centrifuge so loading port (No. 8 in Figure 1-13) is open to the front.	
7. Ensure that centrifuge collar holder is resting on the outer rim of the filler. (See position of centrifuge collar holder in Figure 8-1.) If centrifuge collar holder is not resting on the outer rim of the filler, push filler latching pin (No. 5 in Figure 1-13) toward center of centrifuge, raise filler latch (No. 6 in Figure 1-13), and place it on the outer rim.	
8. Extend centrifuge loop to full length to ensure four-lumen tubing is not twisted.	
9. Fold channel in half.	
10. Thread channel through lower loading port and pull it out from the top.	
11. Position channel in correct orientation above filler slots before placing centrifuge collar (Figure 8-3) into centrifuge collar holder (Figure 8-1).	
12. Load centrifuge collar into centrifuge collar holder, closing cover over collar.	
13. Lower filler latch into locked position.	
14. Press channel into position, ensuring it is completely loaded in filler. Start at the collection chamber and inlet chamber (Figure 8-3) and work around to the opposite side of the channel.	
15. Press tubes into appropriate slots in filler, ensuring all tubes are completely inserted.	
16. Place lower bearing (Figure 8-3) in lower bearing holder (No. 10 in Figure 1-13).	
17. Place upper bearing (Figure 8-3) in upper bearing holder (No. 11 in Figure 1-13).	

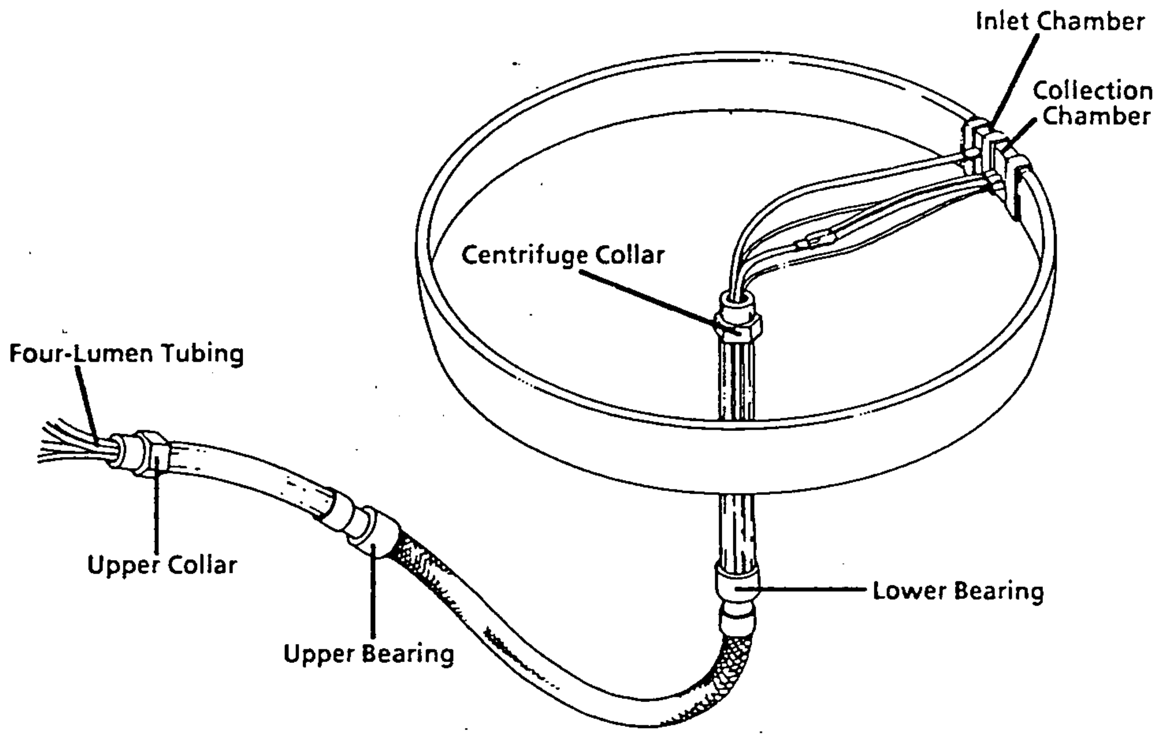

Figure 8-3. WBC Single-Stage Channel

Operator Action	System Action
18. Place upper collar (Figure 8-3) in upper collar holder (No. 12 in Figure 1-13). Ensure that collar is held securely by visually checking that both black sides of holder are equally closed around collar and that an edge between two of the upper collar's six sides is facing out. Be sure that one of the upper collar's six sides is *not* facing out. See Figure 8-4.	
19. Use a "flossing action" to place four-lumen tubing in exit slot on right side of the system.	

WARNING

Inspect all lines, especially those in the centrifuge and on the front panel, to ensure they are not kinked. Lines that are occluded, or partially occluded, may lead to the procedure not operating correctly.

20. Rotate centrifuge several times to ensure tubing does not twist and upper bearing remains in place.

21. Close centrifuge door and cover.

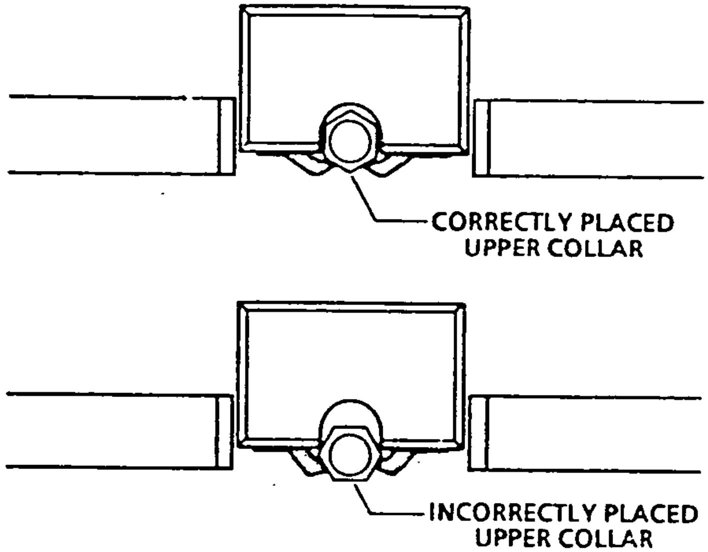

Figure 8-4. Upper Collar Placement

WBC REMOVAL

Operator Action	System Action

Prime Tubing Set

(See Figure 1-11.)

When only single-port saline containers are available and/or hypersensitivity reactions associated with ethylene oxide sterilization must be avoided, see **HOW TO USE AN ALTERNATIVE SINGLE-PASS PRIME PROCEDURE** in SECTION 10 – HELPFUL HINTS.

> Select set: 1 = Platelets or ELP,
> 2 = TPE, 3 = WBC, 4 = RBCX.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

1. Press 3 key to select WBC tubing set.

   If you make a mistake and enter the wrong set number:

   - Press CHANGE MODE key.
   - Press 1 key to select Load Set. The tubing set selection message above is redisplayed.
   - Press the 3 key to select the WBC blood tubing set and continue with Step 2.

> Clamp access and return lines.
> Close both saline lines. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

2. Close white pinch clamps on access and return lines near luer connections. Close roller clamps on access and return saline lines.

Operator Action	System Action
3. Press CONTINUE key.	

> Connect WBC tubing set to
> fluid containers. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

CAUTION

Use aseptic technique throughout this procedure.

4. a. *For MNC procedures:*

   Connect AC line to anticoagulant container, and place AC line in AC level detector.

   b. *For PMN procedures:*

   Connect AC line to hydroxyethyl starch/sodium citrate container (each 500 ml of HES diluted with 30-40 ml of sodium citrate concentrate).

CAUTION

Since HES clears slowly from subjects' bloodstreams following PMN removal procedures and acts as a volume expander, subjects may experience headaches or peripheral edema.

5. Connect inlet and return saline lines : same saline container. Using aseptic technique, clean injection port before inserting metal spike into it. Then place plastic spike in spike port (after removing cover). Fill drip chambers 1/2 full.

CAUTION

Ensure lines are attached to correct fluids:

1. AC line to anticoagulant container.

2. Access and return saline lines to normal saline container.

Visually verify that fluid is flowing through the access, return, and AC spike and drip chambers.

Operator Action	System Action
6. Press CONTINUE key.	

> Open access and return saline lines.
> Press CONTINUE to prime.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

> **WARNING**
>
> **Once fluid has entered the tubing set, do not disturb sensors in pressure sensor housings because this will prevent transducers from monitoring pressures accurately. (See SECTION 12 – RECOVERY PROCEDURES for information on how to load pressure sensors with fluid in tubing set.)**

7. Open access and return saline roller clamps.

8. Press CONTINUE key to prime tubing set.

If Spectra system was not turned off after the last procedure, it will go through a short self-check before beginning Prime.

> Power up tests in progress.

> Priming anticoagulant line.
> (WBC Set) Prime

9. Move bags to correct positions on IV pole as follows:

•	•	•	•	•	•
AC	Saline	Waste	Plasma		WBC Bag

AC Pump	-- 100 ml/min
Inlet Pump	-- Stopped
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Inlet Divert Position
Plasma Valve	-- Collect Position
Collect Valve	-- Collect Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- 30 ml AC
Approximate Time	-- 18 seconds

10. Subject data can be entered before tubing set is primed, during Prime mode, or after priming is complete.

    a. To enter data before Prime mode, select set type (3 = WBC) and press MENU ON/OFF key. Continue with Step 10d.

    b. To enter data during Prime mode, press MENU ON/OFF key. Continue with Step 10d.

Operator Action	System Action

c. To enter subject data after priming is complete, continue with Step 11.

d. Press 1 key to select "Data Entry." (Refer to following section, **Enter Data**, for instructions on how to enter subject information.)

Priming inlet line and air chamber. (WBC Set) Prime

AC Pump	-- Stopped
Inlet Pump	-- 150 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Inlet Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Volume	-- Fluid in Inlet Air Chamber Plus 25 ml
Approximate Time	-- 48 seconds

This step pumps saline through the access saline line, inlet line, and inlet air chamber. To prime the waste line, saline flows for a short time after fluid is detected in the inlet air chamber.

Testing sensors, valves, and pumps. Prime

AC Pump	-- Stopped
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Varies Flow Rate
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Varies Position
Approximate Time	-- 51 seconds

The various valves and pumps change position as the system does a series of self-checks to ensure front panel components have been loaded correctly.

Operator Action	System Action

Priming centrifuge channel. Prime

AC Pump	-- Stopped
Inlet Pump	-- 150 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 100 ml Inlet
Approximate Time	-- 40 seconds

Priming centrifuge channel. Prime

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma Pump	-- 150 ml/min
Collect Pump	-- 5 ml/min
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 250 ml Plasma
Approximate Time	-- 100 seconds

Priming centrifuge channel. Prime

AC Pump	-- Stopped
Inlet Pump	-- 120 ml/ min
Plasma Pump	-- 60 ml/min
Collect Pump	-- 60 ml/min
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 82 ml Inlet
Approximate Time	-- 41 seconds

Operator Action	System Action

Priming centrifuge channel. Prime

AC Pump	-- Stopped
Inlet Pump	-- 120 ml/min
Plasma Pump	-- 60 ml/min
Collect Pump	-- 60 ml/min
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 200 ml Inlet
Approximate Time	-- 100 seconds

Testing sensors, valves, and pumps. Prime

AC Pump	-- Stopped
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Stopped
Collect Pump	-- Varies Flow Rate
Centrifuge	-- 1200 rpm
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Time	-- 12 seconds

Priming return air chamber. Prime

AC Pump	-- 12.5 ml/min
Inlet Pump	-- 150 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- 5 ml/min
Centrifuge	-- 800 rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed
Approximate Volume	-- Fluid in Return Air Chamber Plus 25 ml
Approximate Time	-- 48 seconds

Priming return lines. Prime

AC Pump	-- 12.5 ml/min
Inlet Pump	-- 150 ml/min
Plasma Pump	-- 100 ml/min
Collect Pump	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 50 ml Inlet
Approximate Time	-- 20 seconds

Operator Action	System Action
	Testing sensors, valves, and pumps. Prime

AC Pump	-- Varies Flow Rate
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Varies Flow Rate
Collect Pump	-- Varies Flow Rate
Centrifuge	-- Varies
Waste Valve	-- Varies Position
Plasma Valve	-- Return Position
Collect Valve	-- Varies Position
RBC Line Valve	-- Varies Position
Return Line Valve	-- Varies Position
Approximate Time	-- 60 seconds

The various valves and pumps change position as the system removes air from the channel and does a series of self-checks.

Prime access and return connections.
Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

11. Open white pinch clamp near access luer connection. Allow saline to fill luer lock connection by gravity. Close white pinch clamp.

12. Open white pinch clamp near return luer connection. Allow saline to fill luer lock connection by gravity. Close white pinch clamp.

13. Press CONTINUE key.

Close access saline line. Clamp access line. Press CONTINUE to test AC ratio.

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Operator Action	System Action
14. Use roller clamp to close green-striped access saline line, close white access pinch clamp, and press CONTINUE to test the AC ratio.	

Testing AC ratio. Prime

AC Pump	-- Varies Flow Rate
Inlet Pump	-- Varies Flow Rate
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Time	-- 11 seconds

The AC and inlet pumps change flow rates as the system does a series of self-checks.

WARNING: Do not connect donor/patient before running Alarm Tests. · CONTINUE.

15. Press CONTINUE key to clear this warning from screen.

Perform alarm tests (YES/NO)?

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Time	-- 9 seconds

16. Press YES key to run semiautomatic alarm tests. Refer to SECTION 9 – DIAGNOSTICS for **ALARM TESTS** procedure.

The Spectra system provides an opportunity to verify that key alarm systems are fully operational. Alarm tests will check operation of access pressure sensor, return air detector, return pressure sensor, fluid leak detector, and centrifuge door and cover safety system.

NOTE

To clear saline from return saline drip chamber (so saline drip can be observed), do the following:

1. Clamp line below chamber.
2. Invert container and squeeze saline from drip chamber into saline container.
3. Rehang saline container.
4. Remove clamp.

Operator Action	System Action

Enter Data

WBC procedures will start with following values:

Run Parameter	Value
Time	120 min
MNC Inlet:AC Ratio	12:1
PMN Inlet:AC Ratio	13:1
Collect Rate	3 ml/min

The Spectra control program then uses subject sex, height, weight, and hematocrit to calculate values for the following Run parameters:

Subject Data	Run Parameters
Sex, height, and weight	AC and inlet pump flow rates Centrifuge rpm
Hematocrit	Plasma pump flow rate

You should adjust red cell/plasma interface after Run begins.

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

```
Select sex:   1 = Male,  2 = Female.
   (ENTER = Male)
```

1. Enter subject sex:
   - Press 1 if male.
   - Press 2 if female.
   - Press ENTER for default (data in parentheses).

(English units – enter feet):

```
Enter height,
in feet:   {0}   , and/or inches:   0
```

(Range: 1 to 7 feet)

Operator Action

System Action

2. Enter subject height:

Feet and Inches	Inches	Centimeters
_ feet plus ENTER then _ inches plus ENTER	ENTER then _ inches plus ENTER	_ centimeters plus ENTER
Range: 1-7 ft	Range: 12-84 in.	Range: 30-220 cm

(English units):

```
Enter weight,
in pounds:   {_____}
```

(Range: 10 to 500 lbs)

3. Enter subject weight in pounds (or kilograms). Then press ENTER key.

```
Total blood volume = _________ ml.
(_____ in, _____ lbs, Female). OK (YES/NO)?
```

To confirm input, the Spectra system displays estimated total blood volume and subject data. Total blood volume is calculated from subject data entered into system. The second line of display reviews data input: height, weight, and sex.

4. Confirm subject data input:

- Press NO one time = weight entry display.
  Press NO two times = height entry display.
  Press NO three times = sex entry display.
- Press YES = next display: hematocrit entry display.

```
Enter hematocrit (%): {41}
```

(Range: 10% to 70%)

5. Enter hematocrit as a whole number. (Decimal point is not required.) Then press ENTER.

The Spectra system will use default values of 45% for males and 41% for females.

Operator Action

System Action

Select procedure: 1 = MNC, 2 = ·'MN.
(ENTER = MNC)

6. The Spectra system allows mononuclear or polymorphonuclear cell removal:

   a. Press 1 key or ENTER to select MNC removal.

   b. Press 2 key to select PMN removal.

Inlet volume = _____ml, inlet flow = ___.__,
time = ___min. collect = _____. OK (YES/NO)?

The Spectra system uses subject data (entered by the operator) and microprocessor algorithms to calculate and show the following information on the white cell removal results display:

- Inlet volume displayed in milliliters.
- Inlet pump flow rate displayed in milliliters per minute.
- Procedure time displayed in minutes.
- Collect volume displayed in milliliters.

7. Approve white cell removal values:

   - Press YES = exit subject data entry displays and continue to **Connect Subject** section.
   - Press NO = next display: white cell removal settings menu.

Change: 1 = run time, 2 = inlet flow,
3 = collect volume, 4 = inlet volume.

IMPORTANT: When one value is changed, this will affect other values. For instance, see table on the next page.

Changed Value	Affected Value
Run Time	Inlet Volume Collect Volume AC Volume
Inlet Flow	Inlet Volume AC Volume AC Flow Rate Plasma Flow Rate Collect Volume
Collect Volume	*Collect Pump Flow Rate AC Pump Flow Rate Inlet Pump Flow Rate Plasma Pump Flow Rate Inlet Volume AC Volume
Inlet Volume	Run Time Collect Volume AC Volume

*Things to consider when setting the collect volume include subject WBC and platelet counts as well as fluid balance. Low collect volumes with high WBC and/or platelet counts can cause platelet clumping. Low collect volumes over long procedure times can leave the subject volume expanded due to greater AC flow than collect flow. Low collect volumes may be desirable for certain procedures (e.g., peripheral stem cells).

Operator Action	System Action
8. Select white cell removal value to be changed: • Press 1 = braces around run time • Press 2 = braces around inlet flow • Press 3 = braces around collect volume • Press 4 = braces around inlet volume • Press 9 = redisplays *white blood cell procedure select message* (follows Step 5 above)	Inlet volume = _____ml, inlet flow = ____.__, time = ___min. collect = _____.

Operator Action

System Action

9. Using arrow keys, change selected value. The up arrow key increases the value, and the down arrow key decreases it. Affected value(s) will also be changed. When satisfied that changed and affected values are appropriate, press ENTER to return to *white blood cell removal results message* (precedes Step 7 above).

When changing white blood cell removal values, the following value ranges are allowed for changed values:

Changed Value	Allowed Range
Run Time	10-999 min
Inlet Flow	15-150 ml/min
Collect Volume	10-9999 ml
Inlet Volume	100-32,000 ml

Connect Subject

WARNING

Before connecting subject, check access and return lines for air. If air is present in these lines, do not connect subject. Remove air before starting procedure.

Connect access and return lines. Close access saline. Press CONTINUE to Run.

All Pumps	-- Stopped
Centrifuge	-- 800 rpm
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

1. Perform venipuncture at access and return needle sites.
2. Open white pinch clamps on access and return lines.
3. Leave a saline drip on return line to keep return needle from clotting.
4. Close roller clamp on access saline line.

Operator Action

System Action

Start Run Mode

1. Press CONTINUE key to start system in Run.

All pumps will start and centrifuge speed will increase based on parameters preset by subject data and Spectra algorithms.

AC	Inlet	Plasma	Collect / Replace	Inlet : AC Ratio	Spin RPM
_._	___._	___._	___._	___:_	_____

Diverting prime saline.

AC Pump	-- ___._ ml/min
Inlet Pump	-- ___._ ml/min
Plasma Pump	-- ___._ ml/min
Collect Pump	-- ___._ ml/min
Ratio	-- _ : 1
Centrifuge	-- _____ rpm
Waste Valve	-- Return Divert Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

NOTE

When setting the desired inlet:anticoagulant ratio, consider the following:

12:1 = starting MNC ratio value
13:1 = starting PMN ratio value

The following may be helpful when determining appropriate ratio:

9:1 = (low ratio) normal hematocrit and normal platelet count
15:1 = (high ratio) low hematocrit and low platelet count

Since red blood cells have a buffering capacity, subjects with normal to high hematocrits and normal platelet counts require more anticoagulant to avoid platelet clumping than subjects with low hematocrits and low platelet counts.

If clumping is seen in collect line, lower the inlet:AC ratio or increase the collect pump flow rate.

NOTE

It is normal that a small amount of red cells may be diverted to the waste bag when prime saline is diverted.

2a. If you want to divert the prime saline to the waste bag, continue with Step 3.

OR

2b. If you do not want to divert the prime saline to the waste bag and, instead, want to return it to the subject, follow these steps:

- Press the CHANGE MODE key.
- Press 3 key to select Run.
- Close the roller clamp on the return saline line. (The system will not prompt you to do this.)
- Press CONTINUE key.
- Continue with Step 4, but **do not** press CLEAR.

Operator Action	System Action

System Action

AC	Inlet	Plasma	Collect Replace	Inlet AC Ratio	Spin RPM
_._	___._	___._	___._	___._	_____

Close return saline. Press CLEAR.

AC Pump	-- ___._ ml/min
Inlet Pump	-- ___._ ml/min
Plasma Pump	-- ___._ ml/min
Collect Pump	-- ___._ ml/min
Ratio	-- _ : 1
Centrifuge	-- _____ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Audio: Operator-attention alarm sounds.

3. Use roller clamp to close return saline because blood flow is being returned to subject.

4. Press CLEAR key.

The Spectra control program moves collect valve to collect position after 200 milliliters of blood have been processed.

NOTE

When setting the desired collect pump flow rate, consider the following:

3 ml/min	=	remove large amount of cells
<3 ml/min	=	(low flow) may be desirable for certain procedures (e.g., stem cells). However, there is a higher risk of fluid imbalance and clumping.
>3 ml/min	=	(high flow) deplete buffy coat.

5. Through the centrifuge door view port, observe WBC collect tube (WBC out) to ensure correct removal. (See Figure 8-5.) To establish RBC/ plasma interface at beginning of run, changes in plasma pump flow rate will be frequent and in large increments. As interface becomes established, these changes will be less frequent and in smaller increments.

The system displays initial pump flow rates, anticoagulant ratio, centrifuge rpm, accumulated volumes processed by each pump, procedure time (in minutes), and procedure type.

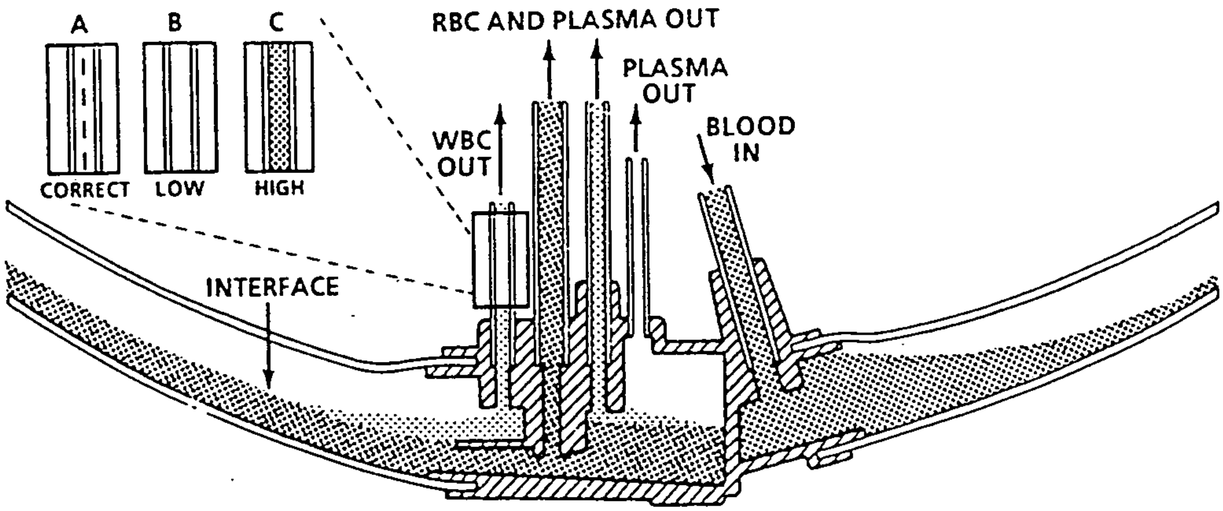

Figure 8-5. Correct Interface Position

Operator Action	System Action
If collecting too deep into red cell layer, WBC collect tube will be filled with red cells. (See Figure 8-5, View C.) To correct this, decrease plasma pump flow rate (in 3 ml/min increments) until quantity of red cells being collected is at desired level. (See Figure 8-5, View A.)	
If not collecting deep enough into white cell layer, WBC collect tube will be clear in color with no red cells present. (See Figure 8-5, View B.) To correct this, increase plasma pump flow rate until quantity of white cells being collected is at desired level. (See Figure 8-5, View A.)	
Once interface is established, smaller and less frequent changes in plasma pump flow rate may be required to maintain interface. Because separation channels require a minute or two to respond to a change in flow rate, changes in plasma pump flow rate should be made gradually (0.5 ml/min changes every 5 to 10 minutes for MNC procedures and 0.2 to 0.3 ml/min changes every 5 to 10 minutes for PMN procedures).	

NOTE

White blood cell removals should ideally have a minimum of red cells and a maximum of white cells. Typically, there is a significant number of white cells and platelets mixed in with innermost layer (top) of red cells. Therefore, it is necessary to collect some red cells to get a maximum white cell yield. WBC collect tube will contain streaks of red cells.

CLI 121806

Operator Action

System Action

AC	Inlet	Plasma	Collect / Replace	Inlet : AC Ratio	Spin RPM
__.__	____.__	____.__	____.__	____.__	______
____	______	______	______	______	MNC
AC	Inlet	Plasma	Collect / Replace	Time Min	Procedure

AC Pump	-- ____.__ ml/min
Inlet Pump	-- ____.__ ml/min
Plasma Pump	-- ____.__ ml/min
Collect Pump	-- ____.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- ______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

If a PMN procedure is being performed, the abbreviation in the bottom right-hand corner of the display screen would be "PMN" rather than "MNC."

Run mode continues until target values are reached.

There are audio and visual warnings when Run mode is complete. The values that have exceeded their limits will be flashing.

End of Run: 1 = Rinseback, 2 = Continue Run.					
____	______	______	______	______	MNC
AC	Inlet	Plasma	Collect / Replace	Time Min	Procedure

AC Pump	-- ____.__ ml/min
Inlet Pump	-- ____.__ ml/min
Plasma Pump	-- ____.__ ml/min
Collect Pump	-- ____.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- ______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

Operator Action	System Action
6. Press 2 key to continue Run mode. (To start Rinseback mode, press 1 key and skip to Start **Rinseback Mode** section.)	If no selection is made, a shutdown alarm will occur after 10 minutes and the pumps will stop.

Increase flashing target limits.
___ ____ ____ ____ ____ Target

AC	Inlet	Plasma	Collect / Replace	Time Min	Procedure

AC Pump -- ___._ ml/min
Inlet Pump -- ___._ ml/min
Plasma Pump -- ___._ ml/min
Collect Pump -- ___._ ml/min
Ratio -- _ : 1
Centrifuge -- _____ rpm
Waste Valve -- Closed
Plasma Valve -- Variable Position
Collect Valve -- Variable Position
RBC Line Valve -- Open
Return Line Valve -- Open

Operator Action	System Action
7. Select flashing target value on bottom row of display.	Inlet volume processed and time elapsed are only values that flash.
8. To increase inlet volume or time, press appropriate key.	
9. Enter new target value on numeric keypad. Then press ENTER.	Run mode continues until target values are reached. There are audio and visual warnings when Run mode is complete.

End of Run: 1 = Rinseback, 2 = Continue Run.
___ ____ ____ ____ ____ MNC

AC	Inlet	Plasma	Collect / Replace	Time Min	Procedure

AC Pump -- ___._ ml/min
Inlet Pump -- ___._ ml/min
Plasma Pump -- ___._ ml/min
Collect Pump -- ___._ ml/min
Ratio -- _ : 1
Centrifuge -- _____ rpm
Waste Valve -- Closed
Plasma Valve -- Variable Position
Collect Valve -- Variable Position
RBC Line Valve -- Open
Return Line Valve -- Open

Start Rinseback Mode

Operator Action	System Action
1. Press 1 key to start Rinseback mode.	If no selection is made, a shutdown alarm will occur after 10 minutes.

> Clamp & disconnect access. Open access saline. Press CONTINUE to Rinseback.

AC Pump	-- ___.__ ml/min
Inlet Pump	-- ___.__ ml/min
Plasma Pump	-- ___.__ ml/min
Collect Pump	-- ___.__ ml/min
Ratio	-- __ : 1
Centrifuge	-- ______ rpm
Waste Valve	-- Closed
Plasma Valve	-- Variable Position
Collect Valve	-- Variable Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

2. Close white pinch clamp on access line. Open roller clamp on green-striped access saline line to allow saline to enter system.

3. Press CONTINUE key to start Rinseback.

> Clamp and disconnect collection bags. Press CLEAR.

AC Pump	-- Stopped
Inlet Pump	-- 50.0 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

4. Disconnect access needle and place in appropriate needle disposal container.

NOTE

If the inlet flow was higher than 50 ml/min during the Run mode, the inlet pump will run at the higher rate.

5. **IMPORTANT**: Clamp or seal collect line and remove WBC bag.

6. Press CLEAR to continue Rinseback.

Operator Action	System Action

Rinseback: Returning RBCs.
Rinse.

AC Pump	-- Stopped
Inlet Pump	-- 50.0 ml/min
Plasma Pump	-- Stopped
Collect Pump	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Volume	-- 90 ml Inlet
Approximate Time	-- 108 seconds

NOTE

If the inlet flow was higher than 50 ml/min during the Run mode, the inlet pump will run at the higher rate.

Red blood cell line is only flow back to subject during this step.

Rinseback: Recirculating.
Rinse.

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma Pump	-- 150.0 ml/min
Collect Pump	-- 50.0 ml/min
Centrifuge	-- Stopped
Waste Valve	-- Recirculate Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed
Approximate Volume	-- 300 ml Plasma
Approximate Time	-- 120 seconds

The Spectra system closes return line valve and flushes red cells off channel wall by recirculating saline through channel at high speed.

NOTE

No flow to or from subject during this step.

Operator Action	System Action

Rinseback: Evacuating channel.
Rinse.

AC Pump	-- Stopped
Inlet Pump	-- Stopped
Plasma Pump	-- 40.0 ml/min
Collect Pump	-- 10.0 ml/min
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 100 ml Plasma
Approximate Time	-- 150 seconds

The Spectra system opens return line valve so free red cells can be returned to subject. Channel is collapsed to reduce extracorporeal blood volume.

Rinseback: Rinsing channel.
Rinse.

AC Pump	-- Stopped
Inlet Pump	-- 50.0 ml/min
Plasma Pump	-- 40.0 ml/min
Collect Pump	-- 10.0 ml/min
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Open
Approximate Volume	-- 150 ml Inlet
Approximate Time	-- 180 seconds

NOTE

If the inlet flow was higher than 50 ml/min during the Run mode, the inlet pump will run at the higher rate.

The Spectra system allows additional saline to enter channel to flush final red cells back to subject.

Disconnect Subject

NOTE

Before disconnecting subject, verify that WBC bag is clamped or sealed and removed.

Operator Action	System Action
	Rinseback completed. Disconnect return line. Close fluids. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Closed
Return Line Valve	-- Closed

1. When Rinseback mode is completed, close white pinch clamp on return line. Disconnect return needle. Close roller clamp on green-striped access saline line.

2. To ensure that fluids do not leak when disposables are removed, when possible,connect return line to collect line (wherecollect bags were disconnected).

3. Press CONTINUE key.

Final values. Press CONTINUE to unload.

AC	Inlet	Plasma	Collect Replace	Time Min	Procedure

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

4. Record on subject records final volumes processed during procedure.

REMOVING WBC DISPOSABLES

Operator Action	System Action

(See Figure 1-13.)

1. Place ends of subject access and return lines in appropriate biohazard disposal container.
2. Press UNLOCK COVER key.
3. Slide centrifuge cover back.
4. Lower centrifuge door.
5. Remove four-lumen tubing from exit slot on right side of system.
6. Remove collar from upper collar holder.
7. Remove upper bearing from upper bearing holder.
8. Remove lower bearing from lower bearing holder.
9. Push filler latching pin toward center of centrifuge and raise filler latch.
10. Pull tubes from slots in filler.
11. Pull channel from filler.
12. Open hinged cover on centrifuge collar holder and remove collar.
13. Raise channel above filler.
14. Fold channel in half and pull through loading port.
15. Discard channel in appropriate biohazard disposal container. (Channel will still be connected to tubing.)
16. Close centrifuge door and cover.

Operator Action	System Action

17. Remove lines from the following:

- Collect and plasma valves
- Return pressure sensor
- Waste divert valve
- RBC line valve
- Return and inlet air detectors
- Centrifuge pressure sensor
- Access pressure sensor
- Return line valve
- Anticoagulant level detector

18. Press CONTINUE key to unload pumps.

> Unloading pumps.
> Unload

All Pumps	-- 48 ml/min
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Load Position
Collect Valve	-- Load Position
RBC Line Valve	-- Open
Return Line Valve	-- Open
Approximate Time	-- 7 seconds

19. Remove lines from cartridge clamps (press clamps up to release pump cartridges).

20. Remove return needle and needle in saline container from tubing set and place them in appropriate needle disposal container.

21. Remove fluid containers and waste bag from Spectra system, and place in disposal appropriate biohazard disposal container along with tubing.

> COBE Spectra (Revision __).
> Press CONTINUE to load tubing set.

SECTION 9 - DIAGNOSTICS

ALARM TESTS

The COBE Spectra™ Apheresis System provides you with an opportunity to verify that the key Spectra alarm systems are fully operational. The alarm tests will check the operation of the sensors, detector circuits, and the associated software. These tests will check the operation of the access pressure sensor, return air detector, return pressure sensor, fluid leak detector, and centrifuge door and cover safety system. These tests are designed to enhance system safety. However, the donor/patient and the Spectra system must still be monitored continuously after the alarm system is tested.

You start the alarm tests by pressing the YES key in response to the question, "Perform alarm tests (YES/NO)?" at the end of the Spectra system's Prime Tubing Set startup procedures. The tests can also be started by pressing the CHANGE MODE key and selecting the 6 key for Diagnostics (invalid during Run and Rinseback modes).

The option not to run the alarm test is offered only for emergencies in which the Spectra system needs to be quickly ready for access.

A tubing set must be primed and loaded to perform these tests successfully. If the tubing set is not loaded and primed, the following message will be displayed:

WARNING: Must have a tubing set loaded and primed to run Alarm Te. .s! CLEAR

Press the CLEAR key to remove this warning message.

The system will automatically sequence through the alarm tests with limited operator interaction, providing each test is passed. If any alarm test fails, the complete alarm test sequence can be repeated. Once the alarm tests are initiated, the Spectra system cannot be used until all these tests are passed.

See SECTION 11 – TROUBLESHOOTING for information on actions to take in response to specific alarms.

Operator Action | **System Action**

Start Alarm Tests

> **WARNING**
>
> **Do not connect donor/patient before running Alarm Tests.**

Before alarm tests actually start, the Spectra system will display the following message for 6 seconds:

> WARNING: Do not connect to donor/patient until Alarm Tests have finished. CONTINUE

1. Press CONTINUE key.

> Clamp access line and access saline.
> Press CONTINUE to start Alarm Tests.

2. a. *For All Procedures Except Single-Needle ELP:*

   Clamp white pinch clamps on access and return lines near needle connections. Close roller clamp on access saline line.

   b. *For Single-Needle ELP Procedures Only:*

   Clamp white pinch clamp between access/return needle and "Y" manifold. Close roller clamp on access saline line.

3. Press CONTINUE key to initiate alarm tests, or press CLEAR key to cancel alarm tests.

Access Pressure Alarm Test

This test will verify operation of access pressure sensor and detection circuit. System will operate inlet and AC pumps to create alarm condition.

> Testing Access Pressure Low alarm.

When the sensor and detection circuit detect that the access pressure low limit is reached, the ACCESS PRESSURE LOW! alarm is generated, and the test of primary return air detection circuit is initiated.

Operator Action	System Action
	ACCESS PRESSURE LOW! Testing primary Return Air alarm.

Primary Return Air Alarm Test

The return air alarm is generated by two independent circuits. The test of the primary circuit is started after successful completion of the access pressure alarm test. Failure in the air detection circuit is generated when the primary detection circuit detects an alarm condition. Then the AIR IN RETURN CHAMBER! alarm is generated.

AIR IN RETURN CHAMBER! Open access saline.	CONTINUE

1. Open roller clamp on access saline line.
2. Press CONTINUE key to go to next test.

Return Pressure Alarm Test

The test will verify operation of the return pressure sensor and detection circuit. The system will operate valves and pumps to create an alarm condition.

Testing Return Pressure High alarm.

When the sensor and detection circuit detect that the high limit of the return pressure is reached, the RETURN PRESSURE HIGH! alarm is generated, and the test of the secondary return air detection circuit is initiated.

RETURN PRESSURE HIGH! Testing secondary Return Air alarm.

Secondary Return Air Alarm Test

When the secondary return air detection circuit detects the presence of air in the return chamber, the AIR IN RETURN CHAMBER! alarm is generated, and the secondary test of air in the return chamber is initiated.

Operator Action	System Action
	AIR IN RETURN CHAMBER! Verify return valve closed CONTINUE
1. Verify return valve is closed. 2. Press CONTINUE key to go to next test.	

Leak Detector Alarm Test and Door Safety System Test

	Wipe fluid leak detector on back wall of centrif..ge basin with damp cloth.
1. Press UNLOCK COVER key. 2. Slide centrifuge cover back. 3. Lower centrifuge door.	
4. Wipe leak detector with slightly damp cloth.	The leak detector circuit will detect the presence of moisture and generate the FLUID LEAK IN CENTRIFUGE! alarm. The system will also verify operation of the door safety system.
	FLUID LEAK IN CENTRIFUGE! Check channel. Dry fluid from sensor. CONTINUE
5. Wipe leak detector with dry cloth.	
6. Close centrifuge door and cover.	If you forget to close the centrifuge door and cover, the following reminder will be displayed:
	Close centrifuge cover.

NOTE

Centrifuge will start immediately after closing door and cover.

7. Press CONTINUE key to continue with **Donor/ Patient Data Entry**.

10-Helpful Hints

SECTION 10 - HELPFUL HINTS

This section contains steps that may be useful during some or all of the apheresis procedures detailed in Sections 3A through 8 of this *Spectra Operator's Manual.*

Some of the steps are included in abbreviated form in Sections 3A through 8 as applicable, but are repeated here for easy reference. For example, each of the nine apheresis procedures sections contains the steps necessary to return the prime saline and those steps are included in this section as well as in those sections.

Some steps, such as those to speed up or slow down Rinseback, are located in this HELPFUL HINTS section only.

This section contains Helpful Hints on the following topics:

- How to correct incorrectly entered tubing set number
- How to return prime saline to donor/patient
- How to use an alternative single-pass prime procedure – Donors allergic to ETO (Do
- How to speed up or slow down Rinseback
- How to determine net additional saline returned to donor/patient by each Spectra apheresis procedure
- How to calculate collect/plasma bag tare weights Calculations·
    - For ELP, Platelet, and WBC Procedures
    - For TPE and RBCX Procedures
- How to expel air from ELP platelet collect bags before start of donor procedure
- How to prepare an ELP double-platelet product
- How to use heparin as TPE anticoagulant
- How to leave a TPE or RBCX patient hypovolemic by a prescribed volume
- How to leave a TPE or RBCX patient isovolumic following Rinseback
- How to collect autologous plasma during a WBC removal procedure
- How to use Spectra system to give a bolus of replacement fluid during a TPE or RBCX procedure
- How to use Spectra system to administer extra replacement fluid during Rinseback
- Abbreviations used in this *Manual*

HOW TO CORRECT INCORRECTLY ENTERED TUBING SET NUMBER

If you accidentally enter the wrong tubing set number at the beginning of the **Prime Tubing Set** section of each apheresis procedure, you can follow the steps below to enter the correct set number up to the time the donor/patient is connected. You can follow these steps even if the pumps are already loaded. If you have actually installed the wrong tubing set, before following the steps below, you would need to press the CHANGE MODE key, press the 5 key to select Unload Set, remove the incorrect set, and install the correct one.

Operator Action	System Action
1. Press CHANGE MODE key.	1 = Load Set, 2 = Prime, 3 = Run, 4 = Rinseback, 5 = Unload Set, 6 = Diagnostics.
2. Press 1 key to select load set.	Select Set: 1 = Platelet or ELP, 2 = TPE, 3 = WBC, 4 = RBCX.
3. Select the number key corresponding to the correct blood tubing set and continue with Step 2 of the **Prime Tubing Set** section of the appropriate apheresis procedure.	

HOW TO CORRECT INCORRECTLY ENTERED TUBING SET NUMBER

If you accidentally enter the wrong tubing set number at the beginning of the **Prime Tubing Set** section of each apheresis procedure, you can follow the steps below to enter the correct set number up to the time the donor/patient is connected. You can follow these steps even if the pumps are already loaded. If you have actually installed the wrong tubing set, before following the steps below, you would need to press the CHANGE MODE key, press the 5 key to select Unload Set, remove the incorrect set, and install the correct one.

Operator Action	System Action
1. Press CHANGE MODE key.	1 = Load Set, 2 = Prime, 3 = Run, 4 = Rinseback, 5 = Unload Set, 6 = Diagnostics.
2. Press 1 key to select load set.	Select Set: 1 = Platelet or ELP, 2 = TPE, 3 = WBC, 4 = RBCX.
3. Select the number key corresponding to the correct blood tubing set and continue with Step 2 of the **Prime Tubing Set** section of the appropriate apheresis procedure.	

HOW TO RETURN PRIME SALINE TO DONOR/PATIENT

If you want to return the prime saline to the donor/patient rather than to the waste bag, follow the steps below:

Operator Action	System Action

1. Perform the first step in the **Start Run Mode** section of each apheresis procedure, which is to press the CONTINUE key to start the Run mode.

AC | Inlet | Plasma | Collect/Replace | Inlet AC Ratio | Spin RPM

```
__.__  ___.__  ___.__  ___.__  ___.__  _____
Diverting prime saline.
```

2. Once the above message has displayed, press the CHANGE MODE key.

```
1 = Load Set, 2 = Prime, 3 = Run,  4 = Rinseback,
5 = Unload Set,  6 = Diagnostics.
```

3. Press 3 key to select run.

This automatically closes the waste valve and opens the return line valve, thus allowing the saline to be returned.

AC | Inlet | Plasma | Collect/Replace | Inlet : AC Ratio | Spin RPM

```
__.__  ___.__  ___.__  ___.__  ___.__  _____
Check run parameters.  Press CONTINUE.
```

4. *For dual-needle procedures only,* close the roller clamp on the return saline line. (The system will not prompt you to do this.)

5. Press the CONTINUE key.

6. Continue with Step 3 of the **Start Run Mode** section for single-needle procedures and Step 4 for dual-needle procedures, but **do not** press CLEAR at the beginning of Step 4.

HOW TO USE AN ALTERNATIVE SINGLE-PASS PRIME PROCEDURE

This single-pass prime procedure is for use with saline containers that provide only a single-port entry. The single-pass prime procedure is an automated prime and debubbling procedure that, rather than recirculating the prime saline, sends the saline to a waste bag attached to the return saline line.

The alternative prime procedure may also be used when hypersensitivity reactions associated with ethylene oxide (EtO) residuals (a by-product of sterilization) are of concern.[1]

Materials:

- Choose the appropriate blood tubing set:
  - Disposable ELP™ blood tubing set (Catalog Number 777003-000)
  - Disposable Platelet blood tubing set (Catalog Number 777004-000)
  - Disposable TPE blood tubing set (Catalog Number 777005-000)
  - Disposable WBC blood tubing set (Catalog Number 777006-000)
  - Disposable RBCX blood tubing set (Catalog Number 777007-000)
- ACD-A anticoagulant: each 100 ml contains:
  - 2.2 g sodium citrate hydrous
  - 730 mg citric acid anhydrous
  - 2.45 g dextrose hydrous
- 0.9% sodium chloride for injection (1000-2000 ml)
- One to two transfer bags (1000 ml each)
- Sampling site coupler.

NOTE

The Single-Needle ELP™ blood tubing set discussed in SECTION 3B – ELP SINGLE-NEEDLE OPERATION uses a version of single-pass prime automatically, putting the prime saline into the waste bag. Thus, it is not necessary to use this procedure with that blood tubing set.

[1] Leitman, S.F., *et al.*, "Allergic Reactions in Healthy Plateletpheresis Donors Caused by Sensitization to Ethylene Oxide Gas," *New England Journal of Medicine, 315*, No. 19, 1192-96 (1986) November 6.

Operator Action	System Action

1. Follow Steps 1-6 of the **Prime Tubing Set** instructions of the ELP, Platelet, and TPE dual-needle procedures, Steps 1-8 of the Platelet and TPE single-needle procedures, and Steps 1-4 of the RBCX and WBC procedures.

2. Connect access saline line to saline container. Using aseptic technique, place plastic spike in spike port (after removing cover). Fill the drip chamber 1/2 full.

3. Using aseptic technique, spike the sampling site coupler to a port on the 1000-ml transfer bag that is hung on IV pole hook.

4. Clean the injection port of the sampling site coupler and insert the metal spike of the return saline line into it.

5. Press CONTINUE key.

> Open access and return saline lines.
> Press CONTINUE to prime.

All Pumps	-- Stopped
Centrifuge	-- Stopped
Waste Valve	-- Load Position
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Closed

WARNING

Once fluid has entered the tubing set, do not disturb sensors in pressure sensor housings because this will prevent transducers from monitoring pressures accurately. (See SECTION 12 - RECOVERY PROCEDURES for information on how to load pressure sensors with fluid in the tubing set.)

6. Open access and return saline roller clamps.

7. Press CONTINUE key to prime tubing set.

The system will now prime the tubing set according to the standard prime procedure.

Operator Action	System Action
	Prime access and return connections. Press CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- 1200 rpm
Waste Valve	-- Closed
Plasma Valve	-- Return Position
Collect Valve	-- Return Position
RBC Line Valve	-- Open
Return Line Valve	-- Open

8. If EtO residuals are a concern, proceed to the next step. If not, proceed to Step 15.

9. Allow the system to remain in pause for a minimum of 15 minutes to allow ethylene oxide residuals to diffuse from the tubing set into the saline.

10. If second prime is desired, press CHANGE MODE key.

> 1 = Load Set, 2 = Prime, 3 = Run, 4 = Rinseback, 5 = Unload Set, 6 = Diagnostics

11. Press 2 to run a second prime.

> Reprime tubing set, (YES/NO)?

12. Press ENTER/YES key.

13. Repeat Steps 10-12 for a third prime. A new saline bag and transfer pack must be attached to the access and return saline lines for a third prime.

CAUTION

Due to the limited volume capacity of the waste bags of the Spectra disposable sets, the Platelet tubing set as modified for single-needle procedures may only be primed a maximum of two times and the Dual-Needle ELP, Platelet, TPE, RBCX, and WBC tubing sets may only be primed a maximum of three times.

14. Once the multiple primes are complete, attach a full saline bag to the access saline line and return saline line to provide fluids during the procedure.

15. To start the prime procedure, proceed with normal prime instructions on display.

HOW TO SPEED UP OR SLOW DOWN RINSEBACK

If you wish to make the Rinseback procedure run faster or slower than the currently set pump speeds, follow the steps below:

1. After clamping and disconnecting the collection bags, press the CLEAR key to continue Rinseback.
2. When Rinseback enters the phase in which you wish to speed up or slow down Rinseback, press the CLEAR key to reveal the pump speeds at that Rinseback phase.

NOTES

- During the Recirculation phase of Rinseback, the return line valve is closed. Therefore, do not make any flow rate adjustments during the Recirculation phase.
- Flow rates are different during each phase of Rinseback. For example, if you increase the inlet flow rate from 50 ml/min to 70 ml/min during the Returning RBCs phase of Rinseback, the 70 ml/min inlet flow rate will only be effective during that phase.

3. Press the flow rate key you wish to change.
4. Enter new value.
5. Press the ENTER key.

NOTE

Since dual-needle and single-needle procedures are identical during Rinseback, this procedure is applicable to both types of procedures.

HOW TO DETERMINE NET ADDITIONAL SALINE RETURNED TO DONOR/PATIENT BY EACH SPECTRA APHERESIS PROCEDURE

Use the following table to determine the net amount of additional saline returned to a donor/patient at the end of Rinseback for each Spectra apheresis procedure.

Procedure	Total Volume of Saline Processed During Rinseback	Amount of Saline Diverted to Waste Bag at Beginning of Divert Prime	Net Additional Saline Returned to Donor / Patient
ELP / Platelet	+ 300 ml	−120 ml	+ 180 ml
TPE / RBCX	+ 345 ml	−150 ml	+ 195 ml
WBC	+ 410 ml	−150 ml	+ 260 ml

HOW TO CALCULATE COLLECT/PLASMA BAG TARE WEIGHTS

For ELP, Platelet, and WBC Procedures

To determine the tare weights of the Spectra product bags and applicable attachments so that you can determine the weight of product for ELP, platelet, and WBC collections, follow the steps below. If a component is not used, do not include it in the calcuation.

		Results
1. Multiply Weight of Product Bag Without Tubing X Number of Bags:		
Collect Bag: 36 grams X _______ (Number of bags)	=	_____________ grams
Plasma Bag: 45 grams X _______ (Number of bags)	=	_____________ grams
2. Multiply Weight of Slide Clamp X Number of Slide Clamps Still Attahced		
2.2 grams X _______ (Number of clamps)	=	_____________ grams
3. Multiply Weight of 1 inch of Tubing X Number of Inches of Tubing Still Attached		
0.35 gram X _______ (Inches of tubing)	=	_____________ grams
4. Add the Totals of Steps 1 to 3 to Obtain a Subtotal		_____________ grams
5. Weight of the Lure	+	0.9 grams
6. Weight of "Y" If Still Attached	+	1.0 grams
7. Add Steps 4, 5, and 6 to Obtain Tare Weight of Product Bag(s) and Applicable Attachments		_____________ **grams**

For TPE and RBCX Procedures

The tare weight of each TPE and RBCX plasma bag, which includes the weight of 11 inches of tubing and one slide clamp, is 89.3 grams.

HOW TO EXPEL AIR FROM ELP PLATELET COLLECT BAGS BEFORE START OF DONOR PROCEDURE

To expel air from the ELP collect bags before the start of a dual-needle or single-needle ELP platelet collect procedure:

Operator Action	System Action
1. After the **Prime Tubing Set** steps and before the **Enter Donor Data** steps, press VALVE key.	
	1 = Return, 2 = RBC, 3 = Waste, 4 = Collect, 5 = Plasma, 6 = All valves.
2. Press 4 to select the collect valve.	
	Collect valve (now returning) 1 = Collect, 2 = Return, 3 = Load.
3. Press 3 to put the collect valve in the Load position.	
4. Use your hands to squeeze air out of both platelet collect bags.	
	The air will be forced out of the platelet collect bags into the waste bag.
5. To return the collect valve to the Return position, press the VALVE key again.	
	1 = Return, 2 = RBC, 3 = Waste, 4 = Collect, 5 = Plasma, 6 = All valves.
6. Press 4 to select the collect valve.	
	Collect valve (now open) 1 = Collect, 2 = Return, 3 = Load.
7. Press 2 to put the collect valve in the Return position.	
8. Press ENTER to remove the message from the screen.	

HOW TO PREPARE AN ELP DOUBLE-PLATELET PRODUCT

To collect ELP double-platelet products during dual-needle and single-needle ELP procedures, there are no changes required in Setup or in the Priming, Data Entry, or Start Run modes. The only changes involve the Start Rinseback mode at the point that the collect bags are to be removed (Step 5 in SECTION 3A – ELP DUAL-NEEDLE OPERATION and Step 4 in SECTION 3B – ELP SINGLE-NEEDLE OPERATION) and the platelet counting technique.

NOTE

The quantity of platelets collected and distributed between the two bags in this procedure is consistent with U.S. Food and Drug Administration guidelines and American Association of Blood Banks standards at the date this *Manual* was printed. Actual yield requirements should be defined by the center's or hospital's standard operating procedures.

1. At Step 5 in SECTION 3A – ELP DUAL-NEEDLE OPERATION and Step 4 in SECTION 3B – ELP SINGLE-NEEDLE OPERATION, seal off and remove the platelet collect bags at a point just above the luer connector that is below the "Y" manifold leading to the bags.
2. At this point to continue Rinseback, continue with Step 6 in SECTION 3A – ELP DUAL-NEEDLE OPERATION and Step 5 in SECTION 3B – ELP SINGLE-NEEDLE OPERATION. The remaining steps of this double-platelet product procedure (Steps 3-9) may be completed after the donor is disconnected.
3. At the end of the dual-needle or single-needle ELP procedure, strip the line between the seal and the bag that currently contains the platelet concentrate.
4. Mix the bag well and refill the lines with homogeneous platelet concentrate by allowing the platelet concentrate to flow back into the lines. (Raising the bags above the lines will speed this process.)
5. Seal off a segment below the "Y" manifold for an initial platelet count.
6. Determine the yield of platelet concentrate using the platelet count and volume of platelet concentrate.
7. If the yield is greater than 6×10^{11}, divide the platelet concentrate into two bags, each containing more than 3.0×10^{11} platelets by transferring half of the well-mixed platelet concentrate into the second collect bag following the steps below:
   a. Ensure that both platelet collect bags are at the same height so that each bag finishes this procedure with an equal volume of platelet concentrate.
   b. Unclamp the tubing to the platelet collect bag to which platelet concentrate is to be transferred.
   c. Allow platelet concentrate to flow to that bag.
   d. If desired, weigh the two platelet product bags before clamping or sealing and removing them to ensure an even division of the platelet product between the two bags.
8. Seal each bag just above the "Y" manifold, separate the bags, and appropriately label each bag.

9. After the platelet collect bags are separated, to ensure that each bag contains the required 3 X 10^{11} platelets, determine the platelet yield in each bag by counting the platelets in a measured volume of homogeneous platelet concentrate. (Before counting, strip and refill the lines with homogeneous platelet concentrate as indicated above.) Seal the line below the collect bag prior to sampling.

HOW TO USE HEPARIN AS TPE ANTICOAGULANT

If clinical requirements make it necessary to use heparin rather than ACD-A as the anticoagulant for TPE procedures, the steps below tell you how to adapt SECTION 6A – TPE DUAL-NEEDLE OPERATION and SECTION 6B – TPE SINGLE-NEEDLE OPERATION for the use of heparin with the Spectra Apheresis System running in the Automatic mode. This heparin TPE procedure should be reviewed with the apheresis physician for each TPE patient to ensure both proper patient management and proper anticoagulation in the extracorporeal blood circuit. This procedure should allow you to maintain an ACT (Activated Clotting Time) of 2.5 to 3.0 minutes in the patient. The patient's ACT should be monitored periodically during the procedure.

Action	Explanation
1. Give patient a preprocedure heparin bolus of 40-60 Units/kg of body weight.	
2. Add enough heparin to 0.9% saline for injection to give a concentration of approximately 14 Units of heparin per ml of saline. For example, add 7 ml of heparin (1000 Units/ml) to 500 ml of 0.9% saline for injection to obtain a concentration of approximately 14 Units of heparin per ml of saline.	The maximum inlet:AC ratio that can be entered directly is 50:1. This 14 Units/ml concentration will allow for a heparin rate of approximately 40 Units/min and an inlet flow rate of between 15 and 150 ml/min.
3. Prime the system following the **Prime Tubing Set** steps in SECTION 6A OR 6B using the heparinized 0.9% saline for injection as the anticoagulant.	
4. After entering the TPE patient data, write down the replacement volume or removal volume information in the exchange run results message.	
5. Connect patient following the **Connect Patient** steps in SECTION 6A or 6B.	
6. Press CONTINUE key to start Spectra in the Run mode. (This is Step 1 of **Start Run Mode** in SECTION 6A or 6B.)	
7. Immediately press the PAUSE key.	This will stop all pumps and display the flow rates on the top line of the display screen.
8. Press INLET FLOW key and change the inlet flow rate to the desired inlet flow rate. Press ENTER.	Steps 8, 9, and 10 force the AC flow rate to 2.9 ml/min, which adds approximately 40 Units/min of heparin to the circuit while achieving the desired inlet flow rate.
9. Press INLET:AC RATIO key and change the ratio to (Inlet Flow ÷ 2.9). Press ENTER.	

Action	Explanation
10. Press the INLET key and change the inlet flow back to the desired flow rate. Press ENTER.	These steps will allow you to change the inlet flow rate while staying in the Automatic mode and will keep the heparin (AC) infusion rate constant at 40 Units of heparin per minute.
11. Press CONTINUE key to continue the TPE Run mode.	The information in the exchange results message will have changed to reflect the modification you made in the inlet flow rate.
12. Press TARGET key to display the TPE target values.	Whenever the inlet flow rate is changed, the replacement and remove fluid volumes are changed and the procedure time is held constant. These steps correct the replacement and remove volume values and change the procedure time to the correct value.
13. Press COLLECT/REPLACE or PLASMA key to place braces around the replacement or removal volume.	
14. Refer to the information you wrote down during Step 4 and use the numeric keypad or arrow keys to change the displayed replacement or removal volume to the volume you wrote down. Press ENTER key.	
15. Press TARGET key to return to the current exchange results message.	
16. Continue with Step 2 of the **Start Run Mode** steps in SECTION 6A or 6B.	

NOTE

Repeat Steps 8-15 if you desire to change the inlet flow rate during the procedure.

HOW TO LEAVE A TPE OR RBCX PATIENT HYPOVOLEMIC BY A PRESCRIBED VOLUME

If the TPE or RBCX patient's physician prescribes that a Spectra dual-needle TPE, single-needle TPE, or RBCX procedure is to leave the patient hypovolemic by a specific volume, follow the steps below:

Operator Action	System Action
1. During the Enter Patient data mode, enter 100% in response to the fluid balance entry message.	
2. Run the TPE or RBCX procedure as usual until all of the replacement fluid is gone and the following message displays:	End of Run: 1 = Rinseback, 2 = Continue Run. ___ ___ ___ ___ ___ XXX AC Inlet Plasma Collect/Replace Time Min Procedure The "XXX" at the bottom right-hand side of the above display is the code for the current apheresis procedure. For example, "RBCX" appears in that location for a red blood cell exchange procedure.
3. Press the PAUSE key.	
4. Press the MANUAL key.	
5. If necessary, press CLEAR to clear the screen and then press the COLLECT/REPLACE FLOW key and enter 0 (zero).	
6. Press the CONTINUE key.	
7. Monitor the Target Plasma or RBC volume until the desired additional volume of fluid has been removed.	
8. Press CHANGE MODE key.	1 = Load Set, 2 = Prime, 3 = Run, 4 = Rinseback, 5 = Unload Set, 6 = Diagnostics.
9. Press 4 key to select Rinseback.	
10. Continue with **Rinseback Mode** steps in TPE or RBCX procedure.	

HOW TO LEAVE A TPE OR RBCX PATIENT ISOVOLEMIC FOLLOWING RINSEBACK

If you need to leave a dual-needle TPE, single-needle TPE, or RBCX patient isovolemic following Rinseback by taking into account the 195 ml of saline returned to them during Rinseback, follow the steps below:

1. *Before the TPE or RBCX procedure begins,* divide 195 by the total volume of replacement fluid to be administered:

$$\frac{195}{\text{Total Replacement Volume}} = \Delta FB$$

2. Convert the result of Step 1 to a percentage by multiplying it by 100:

$$\Delta FB \times 100 = \Delta FB\%$$

3. Subtract the result of Step 2 from 100%. The result is the value you should enter in response to the fluid balance entry message during the **Enter Patient Data** mode of the TPE or RBCX procedure:

$$100\% - \Delta FB\% = \text{Fluid Balance to enter during Patient Data Entry}$$

For example, if 3000 ml of replacement fluid is to be administered:

1. $\frac{195}{3000} = 0.065$
2. $0.065 \times 100 = 6.5\%$
3. $100\% - 6.5\% = 93.5\%$

HOW TO COLLECT AUTOLOGOUS PLASMA DURING A WBC REMOVAL PROCEDURE

Following the steps below will allow you to collect autologous plasma during WBC removal procedures.

NOTE

The plasma valve cannot be moved when running a WBC procedure in the Automatic mode.

Operator Action	System Action
1. Press the MANUAL key to enter the Manual mode.	
2. Press the VALVE key.	1 = Return, 2 = RBC, 3 = Waste, 4 = Collect, 5 = Plasma, 6 = All valves.
3. Press the 5 key to select the plasma valve.	Plasma valve (now returning) 1 = Collect, 2 = Return, 3 = Load.
4. Press 1 to put the plasma valve in the Collect position.	
5. Press the CLEAR key to monitor the volume of plasma being collected.	
6. Repeat Steps 2 through 4, pressing 2 to close the plasma valve by putting it in the Return position.	
7. Press the MANUAL key to return to the Automatic mode.	

HOW TO USE SPECTRA SYSTEM TO GIVE A BOLUS OF REPLACEMENT FLUID DURING A TPE OR RBCX PROCEDURE

The steps below are applicable to dual-needle TPE, single-needle TPE, and RBCX procedures.

1. Record Spectra display values for inlet flow rate and inlet:AC ratio.
2. Press PAUSE key.
3. Press MANUAL key.
4. Press AC FLOW key and enter 0 (zero).
5. Press INLET FLOW key and enter 0 (zero).

NOTE

> If you see the End of Run screen at this point, press CLEAR to bypass it.

6. Press PLASMA/RBC FLOW key and enter 0 (zero).
7. Press COLLECT/REPLACE FLOW key and enter the rate at which you want the bolus of replacement fluid to be administered.
8. Press CONTINUE key.
9. Monitor value of replacement volume until the desired volume of replacement fluid bolus has been administered.
10. Press MANUAL key.
11. The *initial* automatic flow rate values will resume.
12. If, during a TPE or RBCX procedure and before beginning the bolus procedure, you changed the inlet flow rate or AC ratio from its initial automatic values, enter the values you wrote down in Step 1.

HOW TO USE SPECTRA SYSTEM TO ADMINISTER EXTRA REPLACEMENT FLUID DURING RINSEBACK

If, during a dual-needle TPE, single-needle TPE, or RBCX procedure, you need to administer extra replacement fluid during Rinseback, follow the steps below:

1. After clamping and disconnecting the collection bags, press the CLEAR key to continue Rinseback.
2. When Rinseback enters the phase in which you wish to begin administering the extra replacement fluid, press the CLEAR key.

NOTE

During the Recirculation phase of Rinseback, the return line valve is closed. Therefore, you cannot use the Spectra system to administer extra replacement fluid during the Recirculation phase.

3. Press the COLLECT/REPLACE FLOW key.
4. Enter the desired flow rate for replacement fluid during the current Rinseback phase.
5. Press the ENTER key.
6. Repeat Steps 2 through 5 for each phase of Rinseback, except the Recirculation phase, during which you wish to use Spectra to administer extra replacement fluid.
7. Press CLEAR to clear the Rinseback screen and then monitor the collect volume to determine the additional volume of fluid to be replaced.

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ABBREVIATIONS USED IN THIS *MANUAL*

This section contains definitions of the abbreviations used in this *Manual*.

Abbreviation	Definition
AC	*Anticoagulant.* Used in apheresis systems like the Spectra Apheresis System to prevent blood from coagulating.
ACD-A	*Acid-citrate-dextrose* – Formula A. Anticoagulant recommended for use with the Spectra system.
CCM	*Collect Concentration Monitor.* Optical device on the Spectra system that monitors platelet concentration in the collect line to • Display platelet concentration in collect bags. • Display current and predicted end of run platelet yields. • Detect red cell spillovers, thus protecting the platelet product from red cell contamination.
ELP	*Extended life platelets* produced with the Spectra ELP blood tubing set. Because this blood tubing set is functionally closed, donor platelets collected with it can be stored for up to 5 days.
FCR	*Fraction of cells* remaining, specifically, the fraction of a patient's original red blood cells remaining at the end of a red blood cell exchange procedure.
HCT	*Hematocrit.* The ratio of the packed volume of erythrocytes (red blood cells) to the volume of whole blood in a blood sample, expressed as a percentage.

Abbreviation	Definition
HES	*Hydroxyethyl starch.* A sedimenting agent added to anticoagulant during Spectra PMN removal procedures to enhance the separation of granulocytes from red blood cells.
MNC	*Mononuclear cells.* Leukocytes that have nonlobed nuclei, that is, stem cells, monocytes, and lymphocytes. The Spectra system uses this abbreviation in the bottom right-hand corner of message displays to indicate that the information in the message applies to a Spectra MNC removal procedure.
PMN	*Polymorphonuclear* cells. Leukocytes that have multilobed nuclei, that is, granulocytes. The Spectra system uses this abbreviation in the bottom right-hand corner of message displays to indicate that the information in the message applies to a Spectra PMN removal procedure.
PLTC	The Spectra system uses this abbreviation in the bottom right-hand corner of message displays to indicate that the information in the message applies to a Spectra dual-needle ELP or platelet collect procedure.
PLTD	The Spectra system uses this abbreviation in the bottom right-hand corner of message displays to indicate that the information in the message applies to a Spectra platelet deplete procedure.
RBC	*Red blood cells* or erythrocytes.
RBCX	The Spectra system uses this abbreviation in the bottom right-hand corner of message displays to indicate that the information in the message applies to a Spectra red blood cell exchange procedure.

Abbreviation	Definition
SNPLTC	The Spectra system uses this abbreviation in the bottom right-hand corner of message displays to indicate that the information in the message applies to a Spectra single-needle ELP or platelet collect procedure.
SNTPE	The Spectra system uses this abbreviation in the bottom right-hand corner of message displays to indicate that the information in the message applies to a Spectra single-needle therapeutic plasma exchange procedure.
TBV	*Total blood volume*. Calculated by the Spectra system from information provided during Donor/Patient Data Entry on donor/patient weight, height, and sex. TBV is used by Spectra to determine the appropriate anticoagulant flow rate for the donor/patient.
TPE	*Therapeutic plasma exchange*. Spectra's TPE blood tubing set can be used to perform therapeutic plasma exchange procedures on patients with autoimmune diseases or patients about to undergo transplant operations. The Spectra system uses this abbreviation in the bottom right-hand corner of message displays to indicate that the information in the message applies to a Spectra dual-needle therapeutic plasma exchange procedure.
WBC	*White blood cells* or leukocytes.

SECTION 11 - TROUBLESHOOTING

SAFETY SYSTEM

The COBE Spectra™ Apheresis System has a built-in safety system that signals alarm and warning conditions. The severity of the condition determines the type of audible alarm and whether a red alarm LED or yellow warning LED will be lighted.

SHUTDOWN ALARMS

Since system shutdown alarms require your immediate attention, they are indicated by a distinctive chime alarm, a flashing red alarm LED, and a flashing alarm message. Shutdown alarms mean that the pumps are stopped (the system is Paused). In addition, the return line valve may be closed or the centrifuge may be stopped. If the centrifuge is not stopped, its speed will be limited to 1800 rpm after the pumps are off for more than 60 seconds. This is done to reduce temperature rise in the centrifuge loop. When the pumps are restarted, the centrifuge speed will be increased automatically if it has been reduced to 1800 rpm.

Some shutdown alarms can be overridden in the Run mode; others, for safety reasons, can only be overridden in the Rinseback mode. That is, you are allowed to restart the pumps for a limited period of time. When any shutdown alarm message is displayed on the screen, the red alarm LED will flash. If a shutdown alarm has been temporarily overridden, the red alarm LED will be on steady. If the alarm condition persists for a set length of time, the system will again Pause (sounding the audible alarm, flashing the red alarm LED, and displaying the alarm message).

Since shutdown alarms stop the pumps, the PAUSE LED will be on to indicate the system is Paused. If the alarm can be overridden or the problem has been solved, the PAUSE LED will flash and the word CONTINUE will appear on the screen (bottom right-hand corner). Pressing the PAUSE/CONTINUE key will remove the alarm message from the screen and restart the pumps.

If the shutdown alarm cannot be overridden due to safety considerations, the PAUSE LED will be on steady, the word CONTINUE will not appear on the screen, and the PAUSE/CONTINUE key will be inactive. If the CONTINUE key is pressed, the following message will be displayed: "CONTINUE key – must clear alarm first!" In this case, you must take some other action to clear the alarm condition before the pumps can be restarted.

When the alarm message is flashing, the alarm is still active. When the alarm message is no longer flashing, the alarm condition has been removed.

WARNING AND OPERATOR-ATTENTION ALARMS

Warning and operator-attention alarms require you to be aware of the Spectra system's current condition and are indicated by an alarm buzzer and a flashing yellow warning LED. These alarm conditions do not stop the pumps or centrifuge nor do they close the return line valve.

Some warning alarms are automatically cleared when the condition goes away; other warnings are latched on; that is, they must be cleared by pressing a key (usually CLEAR/NO) after the condition has gone away.

Also, some warning alarms can be overridden by pressing the CLEAR/NO key (permanently muting the audible alarm, changing the yellow warning LED from flashing to steady, and clearing the alarm message from the screen). These warning alarms can be overridden for 60 seconds, 20 minutes, or until the end of the procedure. However, the time for 20-minute overrides can vary. If more than one warning is overridden at a time, the last one resets the time back to 20 minutes for all the current overrides. If a warning alarm is reactivated after the override time, the yellow warning LED starts flashing, the screen message is displayed, and the audio alarm is reactivated.

If you cannot clear an alarm following the steps in this Troubleshooting Guide, try turning Spectra's power switch off and on and then pressing the CLEAR or CONTINUE key. If the alarm you cannot clear occurred during Prime:

- Press the CHANGE MODE key.
- Press 1 key to select LOAD SET.
- Enter data and attempt Prime mode again if alarm has cleared.

MULTIPLE ALARMS

An alarm condition created by more than one alarm situation is indicated by an asterisk in the lower right-hand corner of the display screen. The alarm with the highest priority is displayed. Pressing the CLEAR/NO key will display additional alarm messages.

REPEATED SINGLE-NEEDLE ALARMS

Due to the intermittent flow characteristics of single-needle procedures, the draw phase flow can result in pushing controls close to their limits.

If you get a "RETURN PRESSURE HIGH! Decrease return flow scale" alarm near the end of a draw phase and then get a "RETURN FLOW TOO SLOW! Check return. Increase return flow scale." alarm near the end of the next return phase, reduce the inlet flow rate.

These conflicting alarm messages can occur when the single-needle flow rates are too high to support that specific combination of return flow restrictions (single needle, needle position, high return hematocrit, high return pressure, or a restricted return path) combined with the 400-mmHg return pressure limit.

NOTE

If a "RETURN FLOW TOO SLOW..." alarm occurs, always check for the possibility of an infiltration or a blockage at the donor/patient connection site.

TROUBLESHOOTING GUIDE

This Troubleshooting Guide is intended to help you identify and correct alarm conditions that may occur during operation of the Spectra system. No special tools or technical knowledge are required.

Any problem that cannot be identified or remedied through the troubleshooting procedures listed here should be handled by a qualified service technician or COBE Customer Engineering Representative.

Table 11-1 lists all the Spectra alarm message displays. The messages are arranged in alphabetical order along with individual alarm indicators and system actions. The last column of the table shows the page(s) to turn to for more information and a troubleshooting procedure. There may be more than one troubleshooting reference listed if a recovery or maintenance procedure is also applicable.

COBE recommends that you read and understand the conditions described in Table 11-1 as well as the procedures in the Troubleshooting Guide that follows it.

Table 11-1. Spectra Alarms

Alarm Message	Status Lights		Audible Alarm	Pumps Stopped	Centrifuge Stopped	Return Line Valve Closed	Retry, Clear, or Override with CONTINUE	Trouble-shooting Reference
	Red	Yellow						
AC infusion rate configuration was changed last run.	No	Yes	2	No	No	No	No	Page 11-9
AC infusion rate exceeds allowable limits.	No	Yes	2	No	No	No	No	Page 11-10
AC PUMP ERROR!	Yes	No	1	Yes	No	No	Yes, retry	Pages 11-11, 12-2, & 13-2
ACCESS PRESSURE ERROR!	Yes	No	1	Yes	No	No	No	Pages 11-13, 12-2, & 13-2
ACCESS PRESSURE LOW.	No	Yes	2	No	No	No	No	Page 11-14
ACCESS PRESSURE LOW! Check access line and needle.	Yes	No	1	Yes	No	No	Yes, override in Rinseback	Page 11-15
ACCESS PRESSURE OCCLUSION ERROR!	Yes	No	1	Yes	No	No	Yes, retry	Pages 11-16 & 13-2
ACCESS PRESSURE SENSOR DID NOT REACH ALARM LIMIT!	Yes	No	1	Yes	No	No	Yes, retry	Pages 11-17, 12-2, & 13-2
ACCESS PRESSURE SENSOR NOT ZERO!	Yes	No	1	Yes	No	No	Yes, retry	Page 11-19
AIR IN INLET CHAMBER!	Yes	No	1	Yes	No	Yes	Yes, override in Rinseback	Page 11-20
AIR IN RETURN CHAMBER!	Yes	No	1	Yes	No	Yes	No	Pages 11-21 & 12-16
ALARM TEST FAILED!	No	No	None	Yes	Yes	No	Yes, retry	Page 11-22
Battery # __ getting low!	No	Yes	2	No	No	No	No	Page 11-23
CCM CALIBRATION FAILURE.	No	Yes	2	No	No	No	Yes, clear alarm	Page 11-24
CCM INDICATES NO PLATELETS COLLECTED.	No	Yes	2	No	No	No	Yes, clear alarm	Page 11-25
CCM not operational - this run only.	No	No	No	No	No	No	No	Page 11-26

1 Two long rings. . .6 second silence. . .two rings; can be muted for 60 seconds.
2 Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.
3 Two short beeps. . .15 second silence. . .two short beeps; can be muted for 60 seconds.
4 Continuous sound; cannot be muted.

Table 11-1. Spectra Alarms

Alarm Message	Status Lights: Red	Status Lights: Yellow	Audible Alarm	Pumps Stopped	Centrifuge Stopped	Return Line Valve Closed	Retry, Clear, or Override with CONTINUE	Trouble-shooting Reference
CENTRIFUGE COVER OPEN!	Yes	No	1	Yes	Yes	No	Yes, override in Rinseback	Page 11-27
CENTRIFUGE PRESSURE ERROR!	Yes	No	1	Yes	No	No	Yes, retry	Page 11-28
CENTRIFUGE PRESSURE HIGH!	Yes	No	1	Yes	Yes	No	Yes, override in Rinseback	Page 11-29
Centrifuge up to speed.	No	Yes	3	No	No	No	Yes, clear alarm	Page 11-31
Clamp and disconnect collection bags.	No	Yes	3	No	No	No	No	Page 11-32
Close return saline.	No	Yes	3	No	No	No	No	Page 11-33
COLLECT PUMP ERROR!	Yes	No	1	Yes	No	No	Yes, retry	Pages 11-34, 12-29, & 13-2
COLLECT VALVE NOT OPERATING CORRECTLY!	Yes	No	1	Yes	No	No	Yes, retry	Pages 11-36, 12-29, & 13-2
Diagnostic failure prevents operation.	Yes	No	1	Yes	Yes	No	No	Page 11-38
End of Run.	No	Yes	3	No	No	No	No	Page 11-39
End of Run.	Yes	No	1	Yes	No	No	No	Page 11-40
EXCESSIVE LOAD ON CENTRIFUGE!	Yes	No	1	Yes	Yes	No	Yes, override in Rinseback	Page 11-41
EXCESSIVE VIBRATIONS!	Yes	No	1	Yes	Yes	No	Yes, override in Rinseback	Page 11-42
FAILURE #_: ___ ___ ___ __ __	Yes	No	1 or 4, depends on type of failure	Yes	Depends on type of failure	Depends on type of failure	Depends on type of failure	Pages 11-43 & 12-16
FAILURE #19: ___ ___ ___ __ __	Yes	No	See p. 11-45	Yes	Yes	Yes	No	Pages 11-44 & 12-16
FAILURE #20: ___ ___ ___ __ __	Yes	No	See p. 11-45	Yes	Yes	Yes	No	Pages 11-44 & 12-16

1 Two long rings. . .6 second silence. . .two rings; can be muted for 60 seconds.
2 Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.
3 Two short beeps. . .15 second silence. . .two short beeps; can be muted for 60 seconds.
4 Continuous sound; cannot be muted.

Table 11-1. Spectra Alarms

Alarm Message	Status Lights		Audible Alarm	Pumps Stopped	Centrifuge Stopped	Return Line Valve Closed	Retry, Clear, or Override with CONTINUE	Trouble-shooting Reference
	Red	Yellow						
FAILURE IN -5V POWER SUPPLY!	No	Yes	2	No	No	No	No	Page 11-45
FLUID LEAK IN CENTRIFUGE!	Yes	No	1	Yes	Yes	No	Yes, override in Prime or Rinseback	Page 11-46
INLET AND AC PUMP FLOWS NOT BALANCED!	Yes	No	1	Yes	No	No	Yes, retry	Pages 11-49 & 13-2
INLET PUMP ERROR!	Yes	No	1	Yes	No	No	Yes, retry	Pages 11-50, 12-2, 12-29, & 13-2
Invalid replacement fluid volume.	No	Yes	2	No	No	No	No	Pages 11-52 thru 11-54
Invalid process time.	No	Yes	2	No	No	No	No	Pages 11-55 & 11-56
___ ___ key failure!	No	Yes	2	No	No	No	No	Page 11-57
NO RBCs DETECTED.	No	Yes	2	No	No	No	No	Page 11-58
NO SALINE SEEN AT INLET AIR SENSOR!	Yes	No	1	Yes	No	No	Yes, retry	Page 11-59
NO SALINE SEEN AT RETURN AIR SENSOR!	Yes	No	1	Yes	No	No	Yes, retry	Page 11-60
OUT OF ANTICOAGULANT!	Yes	No	1	Yes	No	No	Yes, override in Run and Rinseback	Page 11-61
OVERTORQUE ON _____ PUMP!	Yes	No	1	Yes	No	No	No	Pages 11-62 & 12-16
Plasma and collect pumps running faster than inlet pump.	No	Yes	2	No	No	No	No	Page 11-63
Plasma collection volume exceeds pump speed limits.	No	Yes	2	No	No	No	No	Page 11-64

1 Two long rings. . .6 second silence. . .two rings; can be muted for 60 seconds.
2 Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.
3 Two short beeps. . .15 second silence. . .two short beeps; can be muted for 60 seconds.
4 Continuous sound; cannot be muted.

Table 11-1. Spectra Alarms

Alarm Message	Status Lights Red	Status Lights Yellow	Audible Alarm	Pumps Stopped	Centrifuge Stopped	Return Line Valve Closed	Retry, Clear, or Override with CONTINUE	Trouble-shooting Reference
PLASMA PUMP ERROR!	Yes	No	1	Yes	No	No	Yes, retry	Pages 11-65, 12-29, & 13-2
PLASMA VALVE NOT OPERATING CORRECTLY!	Yes	No	1	Yes	No	No	Yes, retry	Pages 11-67 & 13-2
Post-count in donor may be less than 100,000 platelets/ul.	No	Yes	2	No	No	No	No	Page 11-68
POWER INTERRUPTED!	Yes	No	1	Yes	No	Yes	No	Page 11-69
PUMPS OFF OVER 3 MINUTES.	Yes	No	1	Yes	No	No	Yes, clear alarm	Page 11-70
PUMPS OFF TOO LONG.	Yes	No	1	Yes	No	No	Yes, clear alarm	Page 11-71
PUMPS OFF TOO LONG! Centrifuge turned off for donor/patient safety.	Yes	No	1	Yes	Yes	No	Yes, clear alarm	Page 11-72
Ratio configuration was changed last run.	No	Yes	2	No	No	No	No	Page 11-73
RBCs DETECTED.	No	Yes	2	No	No	No	No	Pages 11-74 & 13-2
RBCs LOST!	Yes	No	1	Yes	No	No	Yes, override in Run and Rinseback	Page 11-75
Restarting centrifuge.	No	Yes	3	Yes	No	No	Yes, clear alarm	Page 11-76
RETURN FLOW TOO FAST! Check return.	Yes	No	1	Yes	No	No	No	Page 11-77
RETURN FLOW TOO SLOW! Check return.	Yes	No	1	Yes	No	No	No	Page 11-79
RETURN PRESSURE HIGH.	No	Yes	2	No	No	No	No	Page 11-81
RETURN PRESSURE HIGH! Check return line and needle.	Yes	No	1	Yes	No	No	Yes, override in Rinseback	Page 11-82

1 Two long rings. . .6 second silence. . .two rings; can be muted for 60 seconds.
2 Three short beeps. . .10 second silence . .three short beeps; can be muted for 60 seconds.
3 Two short beeps. . .15 second silence. . .two short beeps; can be muted for 60 seconds.
4 Continuous sound; cannot be muted.

Table 11-1. Spectra Alarms

Alarm Message	Status Lights		Audible Alarm	Pumps Stopped	Centrifuge Stopped	Return Line Valve Closed	Retry, Clear, or Override with CONTINUE	Trouble-shooting Reference
	Red	Yellow						
RETURN PRESSURE HIGH! Decrease return flow scale.	Yes	No	1	Yes	No	No	Yes, override in Rinseback	Page 11-84
RETURN PRESSURE OCCLUSION ERROR!	Yes	No	1	Yes	No	No	Yes, retry	Pages 11-86 & 13-2
RETURN PRESSURE SENSOR DID NOT REACH ALARM LIMIT!	Yes	No	1	Yes	No	No	Yes, retry	Pages 11-87, 12-29, & 13-2
RETURN PRESSURE SENSOR NOT ZERO!	Yes	No	1	Yes	No	No	Yes, retry	Page 11-89
RETURN VALVE POSITION ERROR!	Yes	No	1	Yes	No	Yes	No	Pages 11-90 & 12-16
Service mode enabled.	No	Yes	2	No	No	No	No	Page 11-91
Spillover detected.	No	Yes	2	No	No	No	No	Page 11-92
Total plasma collected (collect and plasma bags) exceeds specified limit.	No	Yes	2	No	No	No	No	Page 11-93
WASTE VALVE NOT OPERATING CORRECTLY!	Yes	No	1	Yes	No	No	Yes, retry	Page 11-94

1 Two long rings. . .6 second silence. . .two rings; can be muted for 60 seconds.
2 Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.
3 Two short beeps. . .15 second silence. . .two short beeps; can be muted for 60 seconds.
4 Continuous sound; cannot be muted.

AC infusion rate configuration was changed last run.

Alarm Indicators

Alarm Message:

AC infusion rate configuration was changed last run. Please review. CLEAR

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows warning message to be removed by pressing CLEAR key.

Probable Cause	Action
The configured AC infusion rate was changed for the last procedure.	Press the CLEAR key to remove the warning message. The default AC infusion rate entry message is displayed. Either continue to use the AC infusion rate displayed in the message by pressing ENTER or change to a new AC infusion rate between 0.80 and 1.10 ml AC/min/liter of donor/patient TBV. Press ENTER key.

AC infusion rate exceeds allowable limits.

Alarm Indicators

Alarm Message:

AC infusion rate exceeds allowable limits. Flow reduced.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows warning message to be removed by pressing CLEAR key.

For all procedures except RBCX procedures, AC infusion rate lowered to 1.2 ml/min/liter of total blood volume.

For RBCX procedures, AC pump flow rate lowered to 1.4 ml/min/liter of total blood volume.

Inlet flow rate lowered to maintain ratio.

Probable Cause	Action
For all procedures except RBCX, operator increased inlet pump flow rate, causing AC infusion rate to exceed 1.2 ml/min/liter TBV.	Check donor/patient for hypocalcemic symptoms. Donor/patient may need calcium.
For RBCX procedures, operator increased inlet pump flow rate, causing AC pump flow rate to exceed 1.4 ml/min/liter TBV.	
	Press CLEAR key to remove warning message.

AC PUMP ERROR!

Alarm Indicators

Alarm Message:

AC PUMP ERROR! Check for proper loading or leaks. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows retry of AC pump test by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs only during Prime mode testing of AC pump. It indicates that AC pump has failed to develop sufficient pressure as measured by access pressure sensor.	
1. Tubing incorrectly positioned in AC pump, valves, or sensors.	Verify tubing placed correctly in AC pump, valves, and sensors. **NOTE** If access pressure sensor is unloaded while fluid is in the set, refer to Section 12 — RECOVERY PROCEDURES for information on how to properly reload the sensor. Press CONTINUE key to retry AC pump test.
2. Leak in blood tubing.	Check blood tubing to ensure there are no leaks. Press CONTINUE key to retry AC pump test. If alarm recurs, replace tubing set.
3. Leak at access pressure sensor O-ring.	Check access pressure sensor O-ring for wear or damage. Replace if necessary. Refer to **REPLACING PRESSURE SENSOR O-RINGS** in SECTION 13 — MAINTENANCE.

AC PUMP ERROR! (Continued)

Probable Cause	Action
4. Pump, valve, or sensor malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

ACCESS PRESSURE ERROR!

Alarm Indicators

Alarm Message:

ACCESS PRESSURE ERROR! Check saline spike and clamp. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Probable Cause	Action
NOTE This alarm occurs only in Prime mode tests. It indicates that access pressure sensor has failed to detect sufficient head pressure from saline bag.	
1. Access saline clamp not open.	Verify access saline clamp is open.
2. Access pressure sensor not placed in sensor housing.	If there is fluid in the inlet line, refer to the procedure for **ACCESS PRESSURE SENSOR LOADING WITH FLUID IN SET** in SECTION 12 — RECOVERY PROCEDURES.
3. Leak in blood tubing.	Check blood tubing to ensure there are no leaks. If tubing has leaks, replace set and reprime.
4. Leak at access pressure sensor O-ring.	Check access pressure sensor O-ring for wear or damage. Replace if necessary. Refer to **REPLACING PRESSURE SENSOR O-RINGS** in SECTION 13 — MAINTENANCE.
5. Sensor malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

ACCESS PRESSURE LOW.

Alarm Indicators

Alarm Message:

ACCESS PRESSURE LOW.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows 60-second override by pressing CLEAR key.

Probable Cause	Action
NOTE Pressure in access pressure sensor measures 50 mmHg above the access alarm limit: system setting = 200-250 mmHg and operator setting varies (50 mmHg short of shutdown alarm level).	
1. Blockage in inlet line or access needle.	Check for restriction of blood flow in inlet line, for example, kinks, clamps, or clotted access needle.
2. Occluded access vein.	Check access needle site.
3. Inlet pump flow rate too high.	Decrease inlet pump flow rate. If the high-flow option is in effect for this procedure, during the first 500 ml processed, you must reduce the inlet flow rate below 45 ml/min to get it to actually decrease.
4. Access pressure alarm limit too high for current operating conditions.	Decrease access alarm limit if you altered it earlier in the procedure.

ACCESS PRESSURE LOW! Check access line and needle.

Alarm Indicators

Alarm Message:

ACCESS PRESSURE LOW! Check access line and needle.	CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows 60-second override in Rinseback mode by pressing CONTINUE key.

Probable Cause	Action
NOTE Pressure in access pressure sensor measures below specified limit of –250 mmHg or limit set by operator.	
1. Blockage in inlet line or access needle.	Check for restriction of blood flow in inlet line, for example, kinks, clamps, or clotted access needle.
2. Occluded access vein.	Check access needle site.
3. Inlet pump flow rate too high.	Decrease inlet pump flow rate. If the high-flow option is in effect for this procedure, during the first 500 ml processed, you must reduce the inlet flow rate below 45 ml/min to get it to actually decrease.
4. Air accumulation in access saline sterile barrier filter during Rinseback.	Tip filter so that air vent is on top. Squeeze saline bag to force air from filter.
5. Access pressure alarm limit too high for current operating conditions.	Decrease access alarm limit if you altered it earlier in the procedure.

ACCESS PRESSURE OCCLUSION ERROR!

Alarm Indicators

Alarm Message:

ACCESS PRESSURE OCCLUSION ERROR! Check for leakage or open clamps. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows retry of access pressure sensor test by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs only during Prime mode tests. It indicates that access pressure sensor is detecting a pressure drop of more than 50 mmHg, indicative of a leak.	
1. Incompletely closed clamps.	Verify access line, return line, and access saline line are clamped. Press CONTINUE key to retry access pressure sensor test.
2. Leak in access pressure sensor or blood tubing.	Check access pressure sensor and blood tubing to ensure there are no leaks. Press CONTINUE key to retry access pressure sensor test. If alarm recurs, replace tubing set.
3. Leak at access pressure sensor O-ring.	Check access pressure sensor O-ring for wear or damage. Replace if necessary. Refer to **REPLACING PRESSURE SENSOR O-RINGS** in SECTION 13 — MAINTENANCE.
4. Pump malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

ACCESS PRESSURE SENSOR DID NOT REACH ALARM LIMIT!

Alarm Indicators

Alarm Message:

ACCESS PRESSURE SENSOR DID NOT REACH ALARM LIMIT! Check loading. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows retry of access pressure sensor test by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs only in Prime mode tests. It indicates that inlet pump was unable to develop enough negative pressure to reach access pressure sensor alarm limit (–250 mmHg).	
1. Access line or access saline line not clamped.	Verify access line and access saline lines are clamped. Press CONTINUE key to retry access pressure sensor test.
2. Access pressure sensor not placed in sensor housing.	If there is fluid in the inlet line, refer to the procedure for **ACCESS PRESSURE SENSOR LOADING WITH FLUID IN SET** in SECTION 12 – RECOVERY PROCEDURES. Press CONTINUE key to retry access pressure sensor test.
3. Leak in blood tubing set.	Check tubing to ensure there are no leaks. Press CONTINUE key to retry access pressure sensor test. If alarm recurs, replace tubing set.
4. Leak at access pressure sensor O-ring.	Check access pressure sensor O-ring for wear or damage. Replace if necessary. Refer to **REPLACING PRESSURE SENSOR O-RINGS** in SECTION 13 – MAINTENANCE.

ACCESS PRESSURE SENSOR DID NOT REACH ALARM LIMIT! (Continued)

Probable Cause	Action
5. Access pressure sensor, pump, or valve malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

ACCESS PRESSURE SENSOR NOT ZERO!

Alarm Indicators

Alarm Message:

ACCESS PRESSURE SENSOR NOT ZERO! Unload sensor. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Closes return line valve.

Allows retry of access pressure sensor test by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs only during pump loading. It indicates that access pressure sensor is detecting too little or too great a pressure.	
1. Unexpected fluid or pressure in sensor.	Verify blood tubing set is dry and access pressure sensor is correctly loaded. Press CONTINUE key to retry access pressure sensor test.
2. Access pressure sensor malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

AIR IN INLET CHAMBER!

Alarm Indicators

Alarm Message:

AIR IN INLET CHAMBER! Hold 1 key until air is removed. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Closes return line valve.

Allows 60-second override in Rinseback mode by pressing CONTINUE key.

Probable Cause	Action
1. Air or foam in inlet air chamber.	Press and hold 1 key until fluid level rises above inlet air detector and alarm is cleared. If 1 key is held for more than 30 seconds, the system stops air removal. Release key and press 1 again to continue to remove air.
2. Increased centrifuge rpm, causing inlet air chamber to collapse.	Press and hold 1 key until fluid level rises above inlet air detector and alarm is cleared. If 1 key is held for more than 30 seconds, the system stops air removal.
3. Air detector malfunction.	Note alarm message. Discontinue procedure. Press CHANGE MODE key. Select Rinseback. Press CONTINUE key to override alarm during Rinseback mode. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

AIR IN RETURN CHAMBER!

Alarm Indicators

Alarm Message:

AIR IN RETURN CHAMBER! Hold 2 key until air is removed. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Closes return line valve.

Probable Cause	Action
1. Air or foam in return air chamber.	Press and hold 2 key until fluid level rises above return air detector and alarm is cleared. If 2 key is held for more than 30 seconds, the system stops air removal. Release key and press 2 again to continue to remove air.
2. Empty replacement fluid container (TPE and RBCX procedures only).	Replace empty replacement fluid container. Press and hold 2 key until fluid rises above return air detector and alarm is cleared. If 2 key is held for more than 30 seconds, the system stops air removal.
3. Air detector malfunction.	Note alarm message. Press CONTINUE key. If alarm recurs, discontinue procedure. Refer to **MANUAL RINSEBACK PROCEDURE** in SECTION 12 — RECOVERY PROCEDURES. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

ALARM TEST FAILED!

Alarm Indicators

Alarm Message:

ALARM TEST FAILED! Press CONTINUE to retry alarm tests.

Alarm LED: None

Audible Alarm: None

Automatic System Actions

Stops pumps.

Stops centrifuge.

Allows retry of alarm tests by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs during alarm tests.	
1. Any one of the alarm tests has failed.	Check blood tubing set for proper loading. Press CONTINUE to retry alarm tests.
2. Internal system malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

Battery # __ getting low!

Alarm Indicators

Alarm Message:

Battery # __ getting low. Call Field Service to replace.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows removal of warning message by pressing CLEAR key.

Probable Cause	Action
NOTE This warning occurs only during power-up tests.	
Low battery.	Press CLEAR key to remove warning message. Call a qualified service technician or COBE Customer Engineering Representative to replace battery.

CCM CALIBRATION FAILURE.

Alarm Indicators

Alarm Message:

CCM CALIBRATION FAILURE. Press 1 to retry, or CLEAR to disable.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows removal of warning message by pressing CLEAR key.

Probable Cause	Action
NOTE This warning occurs at the end of Prime mode. It indicates that CCM calibration was not successful.	
1. Cuvette incorrectly positioned in Collect Concentration Monitor.	Verify cuvette is placed correctly in CCM. Press 1 key to retry CCM calibration.
2. Bubble in cuvette.	Tap cuvette to move bubble. Press 1 key to retry CCM calibration.
3. Collect Concentration Monitor malfunction.	Note alarm message. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

CCM INDICATES NO PLATELETS COLLECTED.

Alarm Indicators

Alarm Message:

CCM INDICATES NO PLATELETS COLLECTED. Check platelet bag.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows removal of warning message by pressing CLEAR key.

Probable Cause	Action
NOTE This warning occurs after 25% of total blood volume has been processed during Run mode.	
1. Less platelets have been processed than expected.	Verify that donor data are correct. Check the red cell/platelet interface in first stage of platelet channel. Verify that the roller clamp on access saline line is completely closed. Press CLEAR key to remove message.
2. Collect Concentration Monitor malfunction.	Note alarm message. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

CCM not operational - this run only.

Alarm Indicators

Alarm Message:

CCM not operational – this run only.

Alarm LED: None.

Audible Alarm: None.

Automatic System Actions

None.

Probable Cause	Action
NOTE This message appears only if Collect Concentration Monitor display is selected during Run mode and saline calibration had not been successful. A "CCM CALIBRATION FAILURE" alarm should have occurred during Prime mode.	
1. Saline calibration not successful at end of Prime mode due to problem with cuvette installation (bubbles in cuvette or installed incorrectly).	System is usable without CCM. Press CLEAR or MENU ON/OFF key to remove message. Note alarm message.
2. CCM malfunction.	If condition occurs continuously, it indicates a CCM malfunction. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

CENTRIFUGE COVER OPEN!

Alarm Indicators

Alarm Message:

CENTRIFUGE COVER OPEN!	
Close cover.	CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Stops centrifuge.

Allows 60-second override (to start pumps only) in Rinseback mode by pressing CONTINUE key.

Probable Cause	Action
1. Cover left open when centrifuge should be spinning.	Close centrifuge cover and press CONTINUE key to continue procedure.
2. Cover safety latch is not engaged, even though door appears to be closed.	Wiggle cover. Press UNLOCK COVER key and open cover. Close cover and door again.
3. Dust buildup on front door sensor.	For steps to take to remove dust buildup from front door sensor, see **Every Month** subsection of **OPERATOR MAINTENANCE OF SPECTRA™ APHERESIS SYSTEM** of SECTION 13 - MAINTENANCE.
4. Door switch or wiring malfunction.	Note alarm message. Discontinue procedure. Press CHANGE MODE key. Select Rinseback. Press CONTINUE key to override alarm in Rinse-back mode. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

CENTRIFUGE PRESSURE ERROR!

Alarm Indicators

Alarm Message:

CENTRIFUGE PRESSURE ERROR! Check for proper loading. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows retry of centrifuge pressure sensor test by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs only during Prime mode tests. It indicates that centrifuge pressure sensor is not detecting a pressure increase with RBC and waste valves closed.	
1. Tubing incorrectly positioned in centrifuge pressure sensor.	Verify tubing is placed correctly in centrifuge pressure sensor. Press CONTINUE key to retry centrifuge pressure sensor test.
2. RBC or waste valve not loaded.	Verify tubing is placed in RBC and waste valves.
3. Tubing set leak.	Check tubing to ensure there are no leaks. Press CONTINUE key to retry centrifuge pressure sensor test. If alarm recurs, replace tubing set.
4. Sensor, valve, or pump malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

CENTRIFUGE PRESSURE HIGH!

Alarm Indicators

Alarm Message:

CENTRIFUGE PRESSURE HIGH! Check disposables for twisting. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Stops centrifuge.

Allows a 60-second override (to start pumps only) in Rinseback mode by pressing CONTINUE key.

Probable Cause	Action
NOTE Pressure in centrifuge pressure sensor measures above specified limit.	
1. Blockage in inlet or RBC lines.	Check for restriction of blood flow in inlet line and RBC line, for example, kinks, clamps, air, or clotted return needle.
2. Twisted or pinched lines in centrifuge.	Ensure proper installation of four-lumen tubing.
3. For single-needle TPE procedures, instantaneous inlet flow rate is too high. The point at which this alarm occurs will vary with the patient's hematocrit; the higher the patient's hematocrit, the lower the inlet pump speed at which this alarm occurs.	Lower the average inlet flow rate.
4. RBC line valve closed.	Open RBC line valve.

CENTRIFUGE PRESSURE HIGH! (Continued)

Probable Cause	Action
5. Internal system malfunction.	Note alarm message. Press CONTINUE key. If alarm recurs, discontinue procedure. Press CHANGE MODE key. Select Rinseback. Press CONTINUE key to override alarm in Rinse-back mode. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

Centrifuge up to speed.

Alarm Indicators

Alarm Message:

Centrifuge up to speed.   CONTINUE

Alarm LED: Yellow.

Audible Alarm: Buzzer: Two short beeps. . .15 second silence. . .two short beeps; can be muted for 60 seconds.

Automatic System Actions

Pumps are Paused.

Allows clearing alarm by pressing CONTINUE key.

Probable Cause	Action
Operator-attention alarm: generated after CONTINUE key was pressed to restart centrifuge stopped by alarm or STOP SPIN key. Now centrifuge is up to speed again.	Press CONTINUE key to clear alarm and start pumps.

Clamp and disconnect collection bags.

Alarm Indicators

Alarm Message:

Clamp and disconnect connection bags. Press CLEAR.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Two short beeps. . .15 second silence. . .two short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows removal of operator-attention message by pressing CLEAR key.

Probable Cause	Action
Operator-attention alarm: generated when system goes from Rinseback: Collecting to Rinseback: Returning RBCs.	Clamp or seal collect line and remove product bag(s). If source plasma has been collected, clamp or seal plasma line and remove plasma product bag. Press CLEAR key to remove operator-attention message.

Close return saline.

Alarm Indicators

Alarm Message:

Close return saline. Press CLEAR.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Two short beeps. . .15 second silence. . .two short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows removal of operator-attention message by pressing CLEAR key.

Probable Cause	Action
Operator-attention alarm: generated when system completes diverting prime saline step.	For single-needle ELP procedures, close slide clamp on return saline line. For all other procedures, close roller clamp on return saline line. Press CLEAR key to remove operator-attention message.

COLLECT PUMP ERROR!

Alarm Indicators

Alarm Message:

COLLECT PUMP ERROR! Check for proper loading or leaks. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows retry of collect pump test by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs only in Prime mode tests. It indicates that collect pump has failed to develop sufficient pressure at return pressure sensor.	
1. Tubing incorrectly positioned in collect pump or return pressure sensor.	Verify collect pump, valves, and return pressure sensors are loaded correctly. **NOTE** If the return pressure sensor is unloaded while fluid is in the set, refer to **RETURN PRESSURE SENSOR LOADING WITH FLUID IN SET** recovery procedure in SECTION 12 – RECOVERY PROCEDURES for instructions on how to properly reload the return pressure sensor. Press CONTINUE key to retry collect pump test.
2. Plasma, return, waste, RBC, or collect valve misloaded.	Check for proper valve loading.
3. Incorrect tubing set selected.	Press CHANGE MODE, select LOAD, choose correct set type, and reprime.
4. Replacement fluid or collect bag lines clamped.	Verify replacement fluid and collect bag lines are not clamped. Press CONTINUE key to retry collect pump test.

COLLECT PUMP ERROR! (Continued)

Probable Cause	Action
5. Return Flow Controller is incorrectly set.	Check that the Return Flow Controller is fully up in the Prime position.
6. Collect line occluded.	Check that collect line is not kinked, twisted, or pinched. Press CONTINUE key to retry collect pump test.
7. Leak in blood tubing.	Check blood tubing to ensure there are no leaks. Press CONTINUE key to retry collect pump test. If alarm recurs, replace tubing set.
8. Leak at return pressure O-ring.	Check return pressure sensor O-ring for wear or damage. Replace if necessary. Refer to **REPLACING PRESSURE SENSOR O-RINGS** in SECTION 13 – MAINTENANCE.
9. Pump, valve, or sensor malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

COLLECT VALVE NOT OPERATING CORRECTLY!

Alarm Indicators

Alarm Message:

COLLECT VALVE NOT OPERATING CORRECTLY! Check for proper loading. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows retry of collect valve test by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs only in Prime mode tests and is only valid with WBC and Platelet sets. It indicates that collect pump has failed to develop expected pressure at return pressure sensor with collect valve in various positions.	
1. Tubing incorrectly positioned in collect valve or return pressure sensor.	Verify tubing is placed correctly in collect valve and return pressure sensor. **NOTE** If the return pressure sensor is unloaded with fluid in the set, refer to **RETURN PRESSURE SENSOR LOADING WITH FLUID IN SET** recovery procedure in SECTION 12 – RECOVERY PROCEDURES for instructions on how to properly reload the return pressure sensor. Press CONTINUE key to retry collect valve test.
2. Collect bag(s) clamped.	Verify lines leading to collect bag(s) are unclamped.
3. Leak in blood tubing.	Check blood tubing to ensure there are no leaks. Press CONTINUE key to retry collect pump test. If alarm recurs, replace tubing set.

COLLECT VALVE NOT OPERATING CORRECTLY! (Continued)

Probable Cause	Action
4. Return Flow Controller incorrectly set.	Check that the Return Flow Controller is fully up in the Prime position.
5. Leak at return pressure sensor O-ring.	Check return pressure sensor O-ring for wear or damage. Replace if necessary. Refer to **REPLACING PRESSURE SENSOR O-RINGS** in SECTION 13 — MAINTENANCE.
6. Valve or pump malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

Diagnostic failure prevents operation.

Alarm Indicators

Alarm Message:

Diagnostic failure prevents operation. Call Service or re-run Alarm Tests.

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Stops centrifuge.

Closes return line valve.

Probable Cause	**Action**
NOTE At least one alarm test failed, and operator attempted to bypass tests by going into Run mode.	
Run mode was attempted after "ALARM TESTS FAILED!" message was displayed.	Rerun alarm tests. If alarm tests continue to fail, note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

End of Run.

Alarm Indicators

Alarm Message:

End of Run: 1 = Rinseback, 2 = Continue Run.
____ ____ ____ ____ ____ Procedure

Alarm LED: Yellow.

Audible Alarm: Buzzer: Two short beeps. . .15 second silence. . .two short beeps; can be muted for 60 seconds.

Automatic System Actions

None.

Probable Cause	Action
Operator-attention alarm: generated when any value exceeds its target limit.	Press 1 key to start Rinseback mode. OR Press 2 key to continue Run mode.

End of Run.

Alarm Indicators

Alarm Message:

End of Run: 1 = Rinseback, 2 = Continue Run.
___ ___ ___ ___ ___ Procedure

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Probable Cause	Action
Operator did not respond within 10 minutes to operator-attention alarm generated when any value exceeds its target limit.	Press 1 key and CONTINUE key to start Rinseback mode. OR Press 2 key and CONTINUE key to continue Run mode.

EXCESSIVE LOAD ON CENTRIFUGE!

Alarm Indicators

Alarm Message:

EXCESSIVE LOAD ON CENTRIFUGE! Check centrifuge disposables. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Stops centrifuge.

Allows 60-second override (to start pumps only) in Rinseback mode by pressing CONTINUE key.

Probable Cause	Action
1. Improperly installed channel or three/four-lumen tubing.	Verify channel and three/four-lumen tubing are properly installed in centrifuge.
2. Internal system malfunction.	Note alarm message. Press CONTINUE key. If alarm recurs, discontinue procedure. Press CHANGE MODE key. Select Rinseback. Press CONTINUE key to override alarm in Rinseback mode. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

EXCESSIVE VIBRATIONS!

Alarm Indicators

Alarm Message:

EXCESSIVE VIBRATIONS! Check centrifuge disposables. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Stops centrifuge.

Allows 60-second override (to start pumps only) in Rinseback mode by pressing CONTINUE key.

Probable Cause	Action
1. Broken tubing in centrifuge.	Verify tubing in centrifuge is intact.
2. Unbalanced centrifuge.	Verify channel is properly installed in centrifuge. Verify tubing, including upper collar, is properly installed and that the three/four-lumen tubing is not pulled too tightly through exit slot. Verify centrifuge arm is not bent.
3. Internal system malfunction.	Note alarm message. Press CONTINUE key. If alarm recurs, discontinue procedure. Press CHANGE MODE key. Select Rinseback. Press CONTINUE key to override alarm in Rinseback mode. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

FAILURE #__: _____ _____ _____ __ __ (Does not included FAILURE # 19 and FAILURE # 20.)

Alarm Indicators

Alarm Message:

FAILURE #__: _____ _____ _____ __ __ Record #. CONTINUE to retry or Rinseback.

Alarm LED: Red.

Audible Alarm: See below under Automatic System Actions.

Automatic System Actions

Stops pumps.

Depending on alarm, stops centrifuge and/or closes return line valve.

Turns on chime alarm: two rings. . 6 second silence. . .two rings (can be muted for 60 seconds) or turns on chime and buzzer alarm: continuous sound (cannot be muted).

Probable Cause	Action
Internal system malfunction.	Record the entire alarm message as the code and text data it contains could help a qualified service technician or COBE Customer Engineering Representative diagnose the cause of the problem. Press CONTINUE key. If alarm can be cleared, and does not recur, continue procedure. If alarm cannot be cleared, or continues to occur, discontinue procedure. Press CHANGE MODE key. Select Rinseback. Press CONTINUE key to override alarm in Rinseback mode. If alarm cannot be overridden in Rinseback mode, turn off system, and refer to **MANUAL RINSEBACK PROCEDURE** in SECTION 12 – RECOVERY PROCEDURES. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

FAILURE #19: or #20: ____ ____ ____ _ _

Alarm Indicators

Alarm Message:

FAILURE #19: ____ ____ ____ _ _ Record #. Notify Field Service.

FAILURE #20: ____ ____ ____ _ _ Record #. Notify Field Service.

Alarm LED: Red.

Audible Alarm: See below under Automatic System Actions.

Automatic System Actions

Stops pumps.

Stops centrifuge and/or closes return line valve.

Turns on chime alarm: two rings. . 6 second silence. . .two rings (can be muted for 60 seconds) or turns on chime and buzzer alarm: continuous sound (cannot be muted).

Probable Cause	Action
Internal system malfunction.	Turn system off and on to clear alarm. If alarm can be cleared, and does not recur, continue procedure. If alarm cannot be cleared, or continues to occur, discontinue procedure. Refer to **MANUAL RINSEBACK PROCEDURE** in SECTION 12 – RECOVERY PROCEDURES. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

FAILURE IN –5V POWER SUPPLY!

Alarm Indicators

Alarm Message:

FAILURE IN –5V POWER SUPPLY! Write this down. Notify Field Service.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows 60-second override by pressing CLEAR key.

Probable Cause	Action
Internal system malfunction.	Note alarm message. Can continue procedure by overriding alarm with CLEAR key. (The –5 V power supply is used for Collect Concentration Monitor and RBC detector.) Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

FLUID LEAK IN CENTRIFUGE!

Alarm Indicators

Alarm Message:

FLUID LEAK IN CENTRIFUGE! Check channel. Dry fluid from sensor. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Stops centrifuge.

Allows 60-second override in Prime or Rinseback modes by pressing CONTINUE key.

CAUTION

Due to the possible exposure to hepatitis virus, human immunodeficiency virus, and other infectious agents in the handling of extracorporeal blood circuits, adequate precautions should be taken to prevent exposure to and transmission of such agents.

Probable Cause	Action
1. Leak in channel or fluid spilled from above.	Perform the following actions to discontinue procedure: • After centrifuge stops spinning, press UNLOCK COVER key. • Slide cover back and lower door to expose centrifuge chamber. • On advice of medical director, determine if manual Rinseback is appropriate after evaluating the volume of blood loss. • Use a dry cloth to wipe surface of fluid leak detector until it is totally dry. Put cloth in appropriate biohazard disposal container. • Raise door and slide cover closed.

FLUID LEAK IN CENTRIFUGE! (Continued)

Probable Cause	Action
	• Press CLEAR key two or more times, as needed, to clear alarm message and return to flow screen. **NOTE** Do not press CONTINUE key because this restarts centrifuge. If CONTINUE is pressed, immediately press STOP SPIN key. If FLUID LEAK IN CENTRIFUGE! alarm is reactivated, return to the first action. • Press MANUAL key. • Set collect flow rate to 0 ml/min. • Set centrifuge to 0 rpm. • Press CHANGE MODE key. • Select Rinseback. • Follow normal procedures to complete Rinseback and disconnect donor/patient. **NOTE** Alarm messages are cleared for 30 seconds. If alarm messages return while following the above procedure, press CLEAR key to remove messages and return to flow screen. If multiple messages have stacked up, it may be necessary to press CLEAR key several times. **NOTE** If centrifuge loop has become twisted around centrifuge arm, check to ensure arm has not been bent.

FLUID LEAK IN CENTRIFUGE! (Continued)

Probable Cause	Action
2. Residual fluid from prior leak activated alarm when centrifuge started to spin again.	Perform the following actions to dry residual fluid: • Press CONTINUE key to override alarm for 60 seconds. Allow filler to spin dry. • After centrifuge stops spinning, press UNLOCK COVER key. • Slide cover back and lower door to expose centrifuge chamber. • Use a dry cloth to wipe surfaces of centrifuge chamber, fluid leak detector, and filler until they are totally dry. Put cloth in appropriate biohazard disposal container. • Raise door and slide cover closed. • Press CONTINUE key to restart procedure. • Repeat above actions if necessary.
3. Internal system malfunction.	Note alarm message. Press CONTINUE key. If alarm recurs, discontinue procedure. Press CHANGE MODE key. Select Rinseback. Press CONTINUE key to override alarm in Rinseback mode. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

INLET AND AC PUMP FLOWS NOT BALANCED!

Alarm Indicators

Alarm Message:

```
INLET AND AC PUMP FLOWS NOT BALANCED!
Check sensor and pump loading.     CONTINUE
```

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows retry of access pressure sensor test by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs only in Prime mode tests.	
1. Tubing incorrectly positioned in pumps.	Verify tubing is placed correctly in pumps. Press CONTINUE key to retry access pressure sensor test.
2. Access line or access saline line clamps not closed.	Verify access line and access saline line clamps are closed. Press CONTINUE key to retry access pressure sensor test.
3. Leak at access pressure sensor O-ring.	Check access pressure sensor O-ring for wear or damage. Replace if necessary. Refer to **REPLACING PRESSURE SENSOR O-RINGS** in SECTION 13 — MAINTENANCE.
4. Pump or sensor malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

INLET PUMP ERROR!

Alarm Indicators

Alarm Message:

INLET PUMP ERROR! Check for proper loading or leaks. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows retry of inlet pump test by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs only in Prime mode tests. It indicates that inlet pump has failed to develop expected negative pressure at access pressure sensor while priming inlet line.	
1. Tubing incorrectly positioned in inlet pump, valves, or sensors.	Verify tubing is placed correctly in inlet pump, valves, and sensors. **NOTE** If a pressure sensor is unloaded while fluid is in the set, refer to SECTION 12 — RECOVERY PROCEDURES for information on how to properly reload the sensor. Press CONTINUE key to retry inlet pump test.
2. Return, RBC, or waste valve misloaded.	Check for proper valve loading.
3. Leak in blood tubing.	Check blood tubing to ensure there are no leaks. Press CONTINUE key to retry collect pump test.
4. Leak at access pressure sensor O-ring.	Check access pressure sensor O-ring for wear or damage. Replace if necessary. Refer to **REPLACING PRESSURE SENSOR O-RINGS** in SECTION 13 — MAINTENANCE.

INLET PUMP ERROR! (Continued)

Probable Cause	Action
5. Pump, valves, or access sensor malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

Invalid r placement fluid volume.

Alarm Indicators

Alarm Message:

Invalid replacement fluid volume. Increase FCR. CLEAR

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows warning message to be removed by pressing CLEAR key.

Probable Cause	Action
NOTE This warning occurs only during RBCX procedures.	
Using the FCR (fraction red blood cells remaining at the end of a RBCX procedure), the Spectra system cannot calculate a replacement fluid volume that is valid within the constraints of process time and hematocrit.	Press CLEAR and enter a higher FCR (between 1% and 99%) than the one displayed and press ENTER key.

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Invalid replacement fluid volume.

Alarm Indicators

Alarm Message:

Invalid replacement fluid volume.	
Decrease FCR.	CLEAR

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows warning message to be removed by pressing CLEAR key.

Probable Cause	Action
NOTE This warning occurs only during RBCX procedures.	
Using the just-entered FCR (fraction of red blood cells remaining at the end of a RBCX procedure), the Spectra system cannot calculate a replacement fluid volume that is valid within the constraints of process time and hematocrit.	Press CLEAR key and enter a lower FCR (between 1% and 99%) than the one displayed and press ENTER key.

Invalid replacement fluid volume.

Alarm Indicators

Alarm Message:

Invalid replacement fluid volume. Increase end hematocrit.	CLEAR

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows warning message to be removed by pressing CLEAR key.

Probable Cause	Action
NOTE This warning occurs only during RBCX procedures.	
The entered replacement fluid hematocrit is 0 and the entered end hematocrit is lower than can be achieved.	Press CLEAR key and enter a higher end hematocrit (between 10% and 70%) than the one displayed and press the ENTER key.

Invalid process time.

Alarm Indicators

Alarm Message:

Invalid process time. Increase replacement fluid volume.	CLEAR

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows warning message to be removed by pressing CLEAR key.

Probable Cause	Action
NOTE This warning occurs only during RBCX procedures.	
Using the just-entered actual total volume of RBCX replacement fluid, the Spectra system has determined that the desired end hematocrit cannot be reached within the constraint of process time.	Press CLEAR key and enter a higher replacement fluid volume (between 100 and 9999 ml) than the one displayed. OR Change end hematocrit via the MENU ON/OFF key.

Invalid process time.

Alarm Indicators

Alarm Message:

Invalid process time. Decrease replacement fluid volume. CLEAR

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows warning message to be removed by pressing CLEAR key.

Probable Cause	Action
NOTE This warning occurs only during RBCX procedures.	
Using the just-entered actual total volume of RBCX replacement fluid, the Spectra system has determined that the desired end hematocrit cannot be reached with the constraint of process time.	Press CLEAR key and enter a lower replacement fluid volume (between 100 and 9999 ml) than the one displayed. OR Change end hematocrit via the MENU ON/OFF key.

_______ _______ key failure.

Alarm Indicators

Alarm Message:

_______ _______ key failure. Check key operation.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows 20-minute override by pressing CLEAR key.

Probable Cause	Action
1. Key held down.	Release key.
2. Keyboard malfunction.	Note alarm message. Depending on which key has failed, press CLEAR key to override alarm and continue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

NO RBCs DETECTED.

Alarm Indicators

Alarm Message:

NO RBCS DETECTED. Press CLEAR

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows removal of warning message by pressing CLEAR key.

Probable Cause	Action
NOTE This warning occurs only if the system has completed the diverting prime saline step without detecting RBCs during ELP, Platelet, TPE, and WBC procedures.	
1. Line incorrectly positioned in RBC line valve.	Press CLEAR key to remove warning message. Verify RBC line is placed correctly in RBC line valve.
2. No whole blood flowing into system or access saline line not fully closed during run, causing saline to dilute the whole blood entering the system.	Close roller clamp on green access saline line. Press CLEAR key to remove warning message.
3. Patient has a low hematocrit.	Press CLEAR key to remove warning message.
4. Internal system malfunction.	Note alarm message. Press CLEAR key to remove warning message, and continue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

NO SALINE SEEN AT INLET AIR SENSOR!

Alarm Indicators

Alarm Message:

NO SALINE SEEN AT INLET AIR SENSOR! Check sensor for loading. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows retry of priming inlet test by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs only in Prime mode tests if inlet air sensor still detects air after a predetermined time period.	
1. Inlet air chamber not placed in inlet air detector.	Verify inlet air chamber is placed correctly in inlet air detector. Press CONTINUE key to retry priming inlet test.
2. Saline container not connected or access saline line clamp not open.	Verify saline container is connected and access saline line clamp is open. Press CONTINUE key to retry priming inlet test.
3. Pump or sensor malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

NO SALINE SEEN AT RETURN AIR SENSOR!

Alarm Indicators

Alarm Message:

NO SALINE SEEN AT RETURN AIR SENSOR! Check sensor for loading. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows retry of priming return air test by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs only in Prime mode tests if return air sensor still detects air after a predetermined time period.	
1. Return air chamber not placed in return air detector.	Verify return air chamber is placed correctly in return air detector. Press CONTINUE key to retry priming return air test.
2. Air not completely removed from return air chamber.	Use MENU ON/OFF key to select air remove function. Press and hold 2 key.
3. Pump or sensor malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

OUT OF ANTICOAGULANT!

Alarm Indicators

Alarm Message:

OUT OF ANTICOAGULANT! Change container. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows 10-second override in Run mode by pressing CONTINUE key.

Allows override in Rinseback mode by pressing CONTINUE key.

Probable Cause	Action
1. Empty anticoagulant container.	Replace empty AC container. (HES/sodium citrate container for PMN procedures.) Press CONTINUE key to override alarm, allowing time for fluid to reenter AC line. Red alarm LED will turn off when fluid is detected.
2. AC line not placed in level detector.	Place AC line in detector. Press CONTINUE key.
3. AC level detector cable disconnected.	Verify cable is connected. Press CONTINUE key.
4. Internal system malfunction.	Note alarm message. Press CONTINUE key. If alarm recurs, discontinue procedure. Press CHANGE MODE key. Select Rinseback. Press CONTINUE key to override alarm in Rinseback mode. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

OVERTORQUE ON ______ PUMP!

Alarm Indicators

Alarm Message:

OVERTORQUE ON ______ PUMP!	
Check pump tubing.	CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Probable Cause	Action
1. Tubing jammed around pump.	Check tubing in access pump and return pump cartridges. Correct tubing jam. (It may be necessary to unload and load pump cartridges.) Turn pump to verify it moves freely. Press CONTINUE key.
2. Internal system malfunction.	Note alarm message. Press CONTINUE key. If alarm recurs, discontinue procedure. Refer to **MANUAL RINSEBACK PROCEDURE** in SECTION 12 – RECOVERY PROCEDURES. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

Plasma and collect pumps running faster than inlet pump.

Alarm Indicators

Alarm Message:

> Plasma and collect pumps running
> faster than inlet.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows 20-minute override by pressing CLEAR key.

Probable Cause	Action
Operator entered combined plasma pump and collect pump flow rates that are removing blood from the channel faster than it is being pumped in.	Press CLEAR key to override warning. Reduce plasma pump and collect pump flow rates.

Plasma collection volume exceeds pump speed limit.

Alarm Indicators

Alarm Message:

Plasma collection volume exceeds pump speed limit. Plasma volume reduced.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows warning message to be removed by pressing CLEAR key.

Target plasma volume reduced to the maximum that can be pumped in the remaining processing time.

Probable Cause	Action
NOTE This alarm occurs only for platelet collections that are concurrently collecting plasma.	
1. Running at high flow to improve platelet yield.	Press the CLEAR key to remove the warning message. Complete the platelet collection procedure with the target plasma volume automatically set by the system when it determined that the original plasma volume was too high.
2. Entering a large plasma target well into the run.	Press the CLEAR key to remove the warning message. Complete the platelet collection procedure with the target plasma volume automatically set by the system when it determined that the original plasma collection volume was too high.

PLASMA PUMP ERROR!

Alarm Indicators

Alarm Message:

PLASMA PUMP ERROR! Check for proper loading or leaks. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows retry of plasma pump test by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs only in Prime mode tests. It indicates that plasma pump has failed to generate an expected pressure increase at return pressure sensor.	
1. Plasma, return, or RBC valve misloaded.	Verify proper valve loading. Press CONTINUE key to retry plasma pump test.
2. Male/female luer lock (No. 29 in Figures 1-8 and 1-9) not connected.	Make luer connection as appropriate for the blood tubing set you are using. See **Place Tubing on Front Panel** subsection of SECTION 4A or 6A or **Install Single-Needle Bag** subsection of SECTIONS 4B or 6B for instructions on making the proper connection.
3. Incorrect tubing set selected.	Press CHANGE MODE, select LOAD, choose correct set type, and reprime.
4. Plasma line occluded.	Check that plasma line is not kinked, twisted, or pinched. Press CONTINUE key to retry plasma pump test.
5. Plasma line inadvertently placed in RBC valve housing.	Remove plasma line from RBC valve housing and place RBC line in RBC valve.

PLASMA PUMP ERROR! (Continued)

Probable Cause	Action
6. Leak in blood tubing.	Check blood tubing to ensure there are no leaks. Press CONTINUE key to retry lasma pump test. If alarm recurs, replace tubing set.
7. Return Flow Controller incorrectly set.	Check that the Return Flow Controller is fully up in Prime position.
8. Leak at return pressure sensor O-ring.	Check return pressure sensor O-ring for wear or damage. Replace if necessary. Refer to **REPLACING PRESSURE SENSOR O-RINGS** in SECTION 13 – MAINTENANCE.
9. Return pressure sensor not placed in sensor housing or not loaded correctly.	Verify that return pressure sensor is correctly loaded in return pressure sensor housing. If there is fluid in the return line, refer to the procedure for **RETURN PRESSURE SENSOR LOADING WITH FLUID IN SET** in SECTION 12 – RECOVERY PROCEDURES.
10. Pump, valve, or sensor malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

PLASMA VALVE NOT OPERATING CORRECTLY!

Alarm Indicators

Alarm Message:

PLASMA VALVE NOT OPERATING CORRECTLY!
Check for proper loading. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows retry of plasma valve test by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs only in Prime mode tests and is only valid with TPE sets. It indicates that plasma pump has failed to generate expected pressures at return pressure sensor for various plasma valve positions.	
1. Tubing incorrectly positioned in plasma valve.	Verify tubing is placed correctly in plasma valve. Press CONTINUE key to retry plasma valve test.
2. Replacement fluid or collect bag lines clamped.	Verify replacement and collect bag lines are unclamped.
3. Leak at return pressure sensor O-ring.	Check return pressure sensor O-ring for wear or damage. Replace if necessary. Refer to **REPLACING PRESSURE SENSOR O-RINGS** in SECTION 13 — MAINTENANCE.
4. Return Flow Controller incorrectly set.	Check that the Return Flow Controller is fully up in Prime position.
5. Valve or pump malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

Post-count in donor may be less than 100,000 platelets/ul.

Alarm Indicators

Alarm Message:

Post-count in donor may be less than 100,000 platelets/ul.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows permanent override by pressing CLEAR key.

Probable Cause	Action
1. Operator increased the inlet flow rate or procedure time.	Press CLEAR key to override warning. Decrease inlet pump flow rate or procedure time to turn off yellow warning LED.
2. Donor pre-count is too low to support desired yield.	Press CLEAR key to override warning. Decrease inlet pump flow rate or procedure time to turn off yellow warning LED. OR Discontinue procedure.

POWER INTERRUPTED!

Alarm Indicators

Alarm Message:

POWER INTERRUPTED! Continue with previous procedure (YES/NO)?

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Closes return line valve.

Probable Cause	Action
When power is restored after a power interruption, this alarm is generated.	Respond to question: "Continue previous procedure (YES/NO)?" by pressing either ENTER/YES or CLEAR/NO key. If answer is YES, press CONTINUE key to restart interrupted procedure. If answer is NO, press CONTINUE key to unload disposables.

> **WARNING**
>
> **Do not unload disposables if the donor/patient is connected to the Spectra system. If disposables are unloaded while the donor/patient is connected, anticoagulant and other fluids may be infused through the access and return needles.**

PUMPS OFF OVER 3 MINUTES.

Alarm Indicators

Alarm Message:

PUMPS OFF OVER 3 MINUTES. Start saline drip. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows override by pressing CONTINUE key (eliminates condition).

Probable Cause	Action
NOTE This alarm occurs only in Run mode.	
1. Pumps Paused for more than 3 minutes while a donor/patient is connected to system.	Start a saline drip if pumps are to remain Paused. Press CONTINUE key to restart pumps.
2. Return line valve manually closed during a single-needle return phase.	Manually open return line valve. Press CONTINUE to restart pumps.

PUMPS OFF TOO LONG.

Alarm Indicators

Alarm Message:

PUMPS OFF TOO LONG. Centrifuge will turn off in ___ seconds. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows override by pressing CONTINUE key (eliminates condition).

Probable Cause	Action
NOTE This alarm occurs only in Run mode.	
Pumps Paused for more than 9 minutes while centrifuge is running and a donor/patient is connected to system.	Continue saline drip if pumps are to remain Paused. Centrifuge will turn off when time counts down from 60 seconds. Press CONTINUE key to restart pumps.

PUMPS OFF TOO LONG! Centrifuge turned off for donor/patient safety.

Alarm Indicators

Alarm Message:

PUMPS OFF TOO LONG. Centrifuge turned off for donor safety. CONTINUE

PUMPS OFF TOO LONG. Centrifuge turned off for patient safety. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Stops centrifuge.

Allows override by pressing CONTINUE key (eliminates condition).

Probable Cause	Action
NOTE This alarm occurs only in Run mode.	
Pumps Paused for more than 10 minutes while centrifuge is running and a donor/patient is connected to system.	Continue saline drip if pumps are to remain Paused and centrifuge turned off. Press CONTINUE key to restart pumps and centrifuge.

Ratio configuration was changed last run.

Alarm Indicators

Alarm Message:

Ratio configuration was changed last run. Please review. CLEAR

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows warning message to be removed by pressing CLEAR key.

Probable Cause	Action
The configured inlet:AC ratio was changed for the last procedure.	Press the CLEAR key to remove the warning message and display the ratio configuration selection message. Either press ENTER key to continue to use the current default inlet:AC ratio or • Press 1 to change to the "Low" ratio. • Press 2 to change to the "Medium" ratio. • Press 3 to change to the "High" ratio. Press the ENTER key.

RBCs DETECTED.

Alarm Indicators

Alarm Message:

RBCs DETECTED. Check RBC valve for proper loading.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows 60-second override by pressing CLEAR key.

Probable Cause	Action
NOTE This warning occurs only in Prime mode tests and indicates a false detection of RBCs has occurred.	
1. Tubing incorrectly positioned in RBC line valve.	Verify tubing is placed correctly in RBC line valve (pressed firmly in the bottom).
2. Dirty RBC detector.	Clean sensor per approved procedure in SECTION 13 — MAINTENANCE.
3. Reprime selected after blood entered tubing.	Press CLEAR key to override alarm. Continue in Run Mode. Manually close waste divert valve and open return line valve.
4. Internal system malfunction.	Procedure can continue. The Spectra system will use its timeout backup to close waste divert valve and open return line valve. Verify this action. If it does not take place, manually close waste divert valve and open return line valve.

RBCs LOST!

Alarm Indicators

Alarm Message:

RBCs LOST!	
Check for open saline clamps.	CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows 4-minute override in Run Mode by pressing CONTINUE key.

Allows override in Rinseback Mode by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs if RBCs are detected at the start of a single-needle run and the RBC detector later determines that the RBC level has dropped below its initial level.	
1. Access or return saline lines left open.	For single-needle ELP procedures, check to see if slide clamp or return saline line is open. For all other procedures, check to see if the access and/or return saline line roller clamp is open. Close either clamp if open. Press CONTINUE key.
2. Line incorrectly positioned in RBC line valve.	Verify RBC line is placed correctly in RBC line valve (pressed firmly in the bottom). Press CONTINUE key.
3. RBC detector malfunctioning.	Procedure can continue. The Spectra system will use its timeout backup to close waste divert valve and open return line valve. Verify this action. If it does not take place, manually close waste divert valve and open return line valve.

Restarting centrifuge.

Alarm Indicators

Alarm Message:

Restarting centrifuge.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Two short beeps. . .15 second silence. . .two short beeps; can be muted for 60 seconds.

Automatic System Actions

Pumps are Paused.

Probable Cause	Action
Operator-attention alarm: generated after CONTINUE key was pressed to restart centrifuge stopped by alarm or STOP SPIN key.	Press CONTINUE key when "Centrifuge up to speed" message is displayed.

RETURN FLOW TOO FAST!

Alarm Indicators

Alarm Message:

RETURN FLOW TOO FAST! Check return. Decrease return flow scale. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Probable Cause	Action
NOTE This alarm occurs only in a single-needle Run mode.	
1. Return pressure provided by Return Flow Controller needs to be decreased.	Move the return flow scale to a lower value than the value at which it was originally set. Press CONTINUE key.
2. Return Flow Controller may be out of adjustment.	Ensure that the single-needle bag was loaded with no kinked or twisted lines. Verify that the Return Flow Controller returns to the proper Bag Empty position when the single-needle bag is empty. Readjust the Return Flow Controller scale setting so that the return flow indicator is on the 0-7 return flow scale when the single-needle bag is empty.
3. Leak in single-needle bag or lines.	Ensure all luer connections are secure. During single-needle procedures, if the leak is in the single-needle bag or lines of a disposable blood tubing set, replace the set.

RETURN FLOW TOO FAST! (Continued)

Probable Cause	Action
4. Return pressure sensor malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

RETURN FLOW TOO SLOW!

Alarm Indicators

Alarm Message:

RETURN FLOW TOO SLOW! Check return. Increase return flow scale. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Probable Cause	Action
NOTE This alarm occurs only in a single-needle Run mode.	
1. Needle infiltration.	Remove needle and perform a new venipuncture with a new needle. If using either ELP blood tubing set, the product will become a 24-hour platelet product.
2. Blockage in return line or needle.	Check for restrictions of blood flow in return line, for example, kinks, clamps, or clotted access/return needle. Ensure that the single-needle bag is empty, then press the CONTINUE key.
3. Occluded access/return vein.	Check access/return needle site. Reposition or replace needle if necessary. If the needle on either ELP blood tubing set is replaced, the product will become a 24-hour platelet product. Ensure that the single-needle bag is empty, then press the CONTINUE key.
4. Return Flow Controller may be out of adjustment.	Ensure that the single-needle bag was loaded with no kinked or twisted lines. Verify that the Return Flow Controller returns to the proper Bag Empty position when the single-needle bag is empty. Readjust the Return Flow Controller scale setting so that the return flow indicator is on the 0-7 return flow scale when the single-needle bag is empty.

RETURN FLOW TOO SLOW! (Continued)

Probable Cause	Action
5. Return pressure provided by Return Flow Controller needs to be increased.	Ensure that the single-needle bag is empty. Move the return flow scale to a higher value than the value at which it was originally set. Press CONTINUE key.
6. Return pressure sensor malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

NOTE

If you get repeated single-needle alarms, refer to **REPEATED SINGLE-NEEDLE ALARMS** at the beginning of SECTION 11.

RETURN PRESSURE HIGH.

Alarm Indicators

Alarm Message:

RETURN PRESSURE HIGH.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows 60-second override by pressing CLEAR key.

Probable Cause	Action
NOTE Pressure in return pressure sensor measures between +350 and +400 mmHg (50 mmHg short of shutdown alarm level).	
1. Blockage in return line or needle.	Check for restriction of blood flow in return line, for example, kinks, clamps, or clotted return needle.
2. Occluded return vein.	Check return needle site.
3. Needle too small.	Lower inlet pump flow rate.
4. Inlet flow rate too high.	Lower inlet pump flow rate.
5. Return pressure alarm limit is too low for current operating conditions.	Increase return alarm limit if you altered it earlier in the procedure. Be sure the return needle is not infiltrated.
6. Power failure, causing the Spectra system to shut down.	Start saline drip immediately. If power comes back on within a reasonable period of time, perform actions provided for Cause No. 3 on next page. If power does not return within a reasonable period of time, perform manual rinseback and then disconnect donor/patient. See **MANUAL RINSEBACK PROCEDURE** in SECTION 12 – RECOVERY PROCEDURES.

RETURN PRESSURE HIGH! Check return line and needle.

Alarm Indicators

Alarm Message:

RETURN PRESSURE HIGH! Check return line and needle. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .10 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows 60-second override in Rinseback mode by pressing CONTINUE key.

Probable Cause	Action
NOTE Pressure in return pressure sensor measures above specified limit of +400 mmHg.	
1. Blockage in return line or needle.	Check for restriction of blood flow in return line, for example, kinks, clamps, or clotted return needle.
2. Return pressure alarm limit is too low for current operating conditions.	Increase return alarm limit if you altered it earlier in the procedure. Be sure the return needle is not infiltrated.
3. Buildup of pressure in system caused by an alarm condition or steps taken by operator that cause the centrifuge to stop.	Release the pressure in the system by following one of the two sets of steps below: 1. To release the pressure into the tubing set: a. Use the white pinch clamp on the return line or a tube-occluding forceps to close the return line near the return needle. b. Open roller clamp on return saline line. c. Manually pull out the return line valve. d. Use the roller clamp to close the return saline line and either open the white pinch clamp you closed in Step 1a or remove the tube-occluding forceps you placed on the return line in Step 1a. e. Press CONTINUE key.

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RETURN PRESSURE HIGH! Check return line and needle (Continued)

Probable Cause	Action
	OR 2. To release the pressure into the waste bag: a. Open waste divert valve to relieve pressure by • Pressing MENU ON/OFF key • Pressing 4 to select air remove • Pressing 2 to select return divert position b. Close waste divert valve to return to operating position by • Releasing 2 key • Pressing CONTINUE key
4. Occluded return vein.	Check return needle site.
5. Needle too small.	Lower inlet pump flow rate.
6. Inlet flow too high.	Lower inlet pump flow rate.
7. Internal system malfunction.	Note alarm message. Press CONTINUE key. If alarm recurs, discontinue procedure. Press CHANGE MODE key. Select Rinseback. Press CONTINUE key to override alarm in Rinseback mode. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

RETURN PRESSURE HIGH! Decrease return flow scale.

Alarm Indicators

Alarm Message:

RETURN PRESSURE HIGH! Decrease return flow scale. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .10 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows 60-second override in Rinseback mode by pressing CONTINUE key.

Probable Cause	Action
NOTES This alarm occurs only in a single-needle Run mode. Pressure in return pressure sensor measures above specified limit of +400 mmHg.	
1. Return Flow Controller's return flow scale is set too high.	Decrease the return flow scale setting. If you receive a RETURN FLOW TOO SLOW! alarm at the end of the next return phase, allow the single-needle bag to empty. Then decrease the inlet pump flow rate for the current donor/patient. Press CONTINUE key.
2. Blockage in access/return line or needle.	Check for restriction of blood flow in access/return line, for example, kinks, clamps, or clotted needle.
3. Buildup of pressure in system caused by an alarm condition or steps taken by operator that cause the centrifuge to stop.	Release the pressure in the system by following one of the two sets of steps below: 1. To release the pressure into the tubing set: a. Use the white pinch clamp on the return line or a tube-occluding forceps to close the return line near the return needle. b. Open roller clamp on return saline line.

RETURN PRESSURE HIGH! Decrease return flow scale (Continued)

Probable Cause	Action
	c. Manually pull out the return line valve.
	d. Use the roller clamp to close the return saline line and either open the white pinch clamp you closed in Step 1a or remove the tube-occluding forceps you placed on the return line in Step 1a.
	e. Press CONTINUE key.
	OR
	2. To release the pressure into the waste bag:
	a. Open waste divert valve by • Pressing MENU ON/OFF key • Pressing 4 to select air remove • Pressing 2 to select return divert position
	b. Close waste divert valve by • Releasing 2 key • Pressing CONTINUE key
4. Needle too small.	Lower inlet pump flow rate.
5. Inlet flow too high.	Lower inlet pump flow rate.
6. Internal system malfunction.	Note alarm message. Press CONTINUE key. If alarm recurs, discontinue procedure. Press CHANGE MODE key. Select Rinseback. Press CONTINUE key to override alarm in Rinseback mode. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

NOTE

If you get repeated single-needle alarms, refer to **REPEATED SINGLE-NEEDLE ALARMS** at the beginning of SECTION 11.

RETURN PRESSURE OCCLUSION ERROR!

Alarm Indicators

Alarm Message:

RETURN PRESSURE OCCLUSION ERROR! Check for leakage. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows retry of return pressure sensor test by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs only in Prime mode tests. It indicates that return pressure sensor is detecting a pressure drop of more than 50 mmHg, indicative of a leak.	
1. Leak in access pressure sensor or blood tubing.	Check access pressure sensor and blood tubing to ensure there are no leaks. Press CONTINUE key to retry return pressure sensor test. If alarm recurs, replace tubing set.
2. Leak at return pressure sensor O-ring.	Check return pressure sensor O-ring for wear or damage. Replace if necessary. Refer to **REPLACING PRESSURE SEN OR O-RINGS** in SECTION 13 — MAINTENANCE.
3. Pump malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

RETURN PRESSURE SENSOR DID NOT REACH ALARM LIMIT!

Alarm Indicators

Alarm Message:

RETURN PRESSURE SENSOR DID NOT REACH ALARM LIMIT! Check loading. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows retry of return pressure sensor test by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs only in Prime mode tests. It indicates that inlet pump has failed to develop sufficient pressure at return pressure sensor.	
1. Return pressure sensor not placed in sensor housing or not loaded correctly.	Verify that return pressure sensor is correctly loaded in return pressure sensor housing. If there is fluid in the return line, refer to the procedure for **RETURN PRESSURE SENSOR LOADING WITH FLUID IN SET** in SECTION 12 — RECOVERY PROCEDURES. Press CONTINUE key to retry return pressure sensor test.
2. Leak in blood tubing set.	Check tubing to ensure there are no leaks. Press CONTINUE key to retry return pressure sensor test. If alarm recurs, replace tubing set.
3. Leak at return pressure sensor O-ring.	Check return pressure sensor O-ring for wear or damage. Replace if necessary. Refer to **REPLACING PRESSURE SENSOR O-RINGS** in SECTION 13 — MAINTENANCE.
4. Tubing incorrectly loaded in return, RBC, or waste valve.	Check for correct loading.

RETURN PRESSURE SENSOR DID NOT REACH ALARM LIMIT! (Continued)

Probable Cause	Action
5. Return Flow Controller incorrectly set.	Check that the Return Flow Controller is fully up in the Prime position.
6. Return pressure sensor, pump, or valve malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

RETURN PRESSURE SENSOR NOT ZERO!

Alarm Indicators

Alarm Message:

```
RETURN PRESSURE SENSOR NOT ZERO!
Unload sensor.                    CONTINUE
```

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Closes return line valve.

Allows retry of return pressure sensor test by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs only during pump loading. It indicates that return pressure sensor is detecting too little or too great a pressure.	
1. Unexpected fluid or pressure in sensor.	Verify blood tubing set is dry and return pressure sensor is correctly loaded. Press CONTINUE key to retry return pressure sensor test.
2. Return pressure sensor malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

RETURN VALVE POSITION ERROR!

Alarm Indicators

Alarm Message:

RETURN VALVE POSITION ERROR! Check for obstructions. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Closes return line valve.

Probable Cause	Action
1. Valve pushed in or held out.	Move valve to correct position.
2. Valve obstructed.	Verify no obstructions in return line valve.
3. Internal system malfunction.	Note alarm message. Press CONTINUE key. If alarm recurs, discontinue procedure. Refer to **MANUAL RINSEBACK PROCEDURE** in SECTION 12 — RECOVERY PROCEDURES. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

Service mode enabled.

Alarm Indicators

Alarm Message:

Service mode enabled. Stop procedure. Notify Field Service.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

None.

CAUTION

System should not be used for a donor/patient procedure while in Service mode.

Probable Cause	Action
Switches left on that enable service mode or disable system ERROR alarms.	Note alarm message. Wait 60 seconds for yellow alarm LED to stop flashing. Press CLEAR key. (Service mode is disabled for this procedure.) Continue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

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Spillover detected.

Alarm Indicators

Alarm Message:

Spillover detected. Returning collect. Press ENTER to collect when line clears.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Places collect valve in return position.

Increases collect pump flow rate and decreases plasma pump flow rate.

Probable Cause	Action
1. Red cells spilled over into second stage of channel.	Monitor collect line to verify it is red. If red, wait for it to clear. Assist RBC removal by tapping tubing. When clear through collect valve, press ENTER key to start collecting again.
2. CCM sensor malfunction.	Monitor collect line to verify it is red. If not red, press ENTER key to start collecting again. If false warning recurs, turn off CCM using MENU ON/OFF key selections. At end of procedure, clean lenses with a cotton swab. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

Total plasma collected (collect and plasma bags) exceeds specified limit.

Alarm Indicators

Alarm Message:

Total plasma collected (collect and plasma bags) exceeds specified limit.

Alarm LED: Yellow.

Audible Alarm: Buzzer: Three short beeps. . .10 second silence. . .three short beeps; can be muted for 60 seconds.

Automatic System Actions

Allows permanent override by pressing CLEAR key.

Probable Cause	Action
Operator increased plasma collection volume beyond default total for plasma configuration value.	Press CLEAR key to remove warning message. Lower plasma or platelet collect volume or shorten procedure time. **NOTE** Check regulations for allowable plasma volumes that can be removed from a donor.

WASTE VALVE NOT OPERATING CORRECTLY!

Alarm Indicators

Alarm Message:

WASTE VALVE NOT OPERATING CORRECTLY! Check for proper loading. CONTINUE

Alarm LED: Red.

Audible Alarm: Chime: Two rings. . .6 second silence. . .two rings; can be muted for 60 seconds.

Automatic System Actions

Stops pumps.

Allows retry of waste valve test by pressing CONTINUE key.

Probable Cause	Action
NOTE This alarm occurs only in Prime mode tests. It indicates that centrifuge pressure sensor did not measure expected pressures with waste valve in various positions.	
1. Tubing incorrectly positioned in waste valve.	Verify tubing is placed correctly in waste valve. Press CONTINUE key to retry waste valve test.
2. Tubing incorrectly positioned in centrifuge pressure sensor.	Verify tubing is placed correctly in centrifuge pressure sensor. Press CONTINUE key to retry test.
3. Tubing incorrectly positioned in return, RBC, or plasma valve.	Check for proper loading.
4. Valve or pump malfunction.	Note alarm message. Discontinue procedure. Notify qualified service technician or COBE Customer Engineering Representative of alarm message.

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SECTION 12 - RECOVERY PROCEDURES

RECOVERY PROCEDURES

The following recovery procedures are intended to help you bring the COBE Spectra™ Apheresis System back into safe operating condition after. for example, an alarm has been cleared. Or, if an alarm cannot be cleared and override in Rinseback is not allowed, the MANUAL RINSEBACK PROCEDURE will help you safely return blood to the donor/patient.

These recovery procedures also include the steps for converting a dual-needle Platelet or TPE procedure to a single-needle procedure after the procedure has already been started as a dual-needle procedure. This conversion can take place up to the Rinseback mode. If you have told the Spectra system that you want to do a single-needle Platelet or TPE procedure, up to the time the Prime mode is completed you can change your mind and go back to running a dual-needle Platelet or TPE procedure. Steps for this backout procedure are also provided.

The usual reason for converting a procedure started as a dual-needle operation to a single-needle operation is to accommodate a donor or patient who has only one good venipuncture site.

COBE recommends that you read and understand all of these recovery procedures.

The following recovery procedures are provided in this section:

- Access pressure sensor loading with fluid in set
- Dual needle to single needle conversion procedures:
  - During Prime mode prior to donor/patient connection
  - During Run mode
- Manual override of centrifuge cover and door latches
- Manual rinseback procedure
- Manual spillover recover procedures for dual-needle and single-needle platelet procedures
- Power up tests failure
- Red cell accumulation in TPE channel
- Red cell accumulation in RBCX channel
- Return pressure sensor loading with fluid in set
- Single needle to dual needle backout procedure

DUAL NEEDLE TO SINGLE NEEDLE CONVERSION PROCEDURES

Normally you would choose to run a Platelet or TPE procedure as a single-needle operation immediately after you select the type of blood tubing set to use. However, upon connecting some donors or patients to the Spectra system, you may find that they have only one good venipuncture site. In such situations, you may want to convert the Platelet or TPE procedure from dual-needle to single-needle operation. To perform this conversion, follow these steps:

Operator Action	System Action

1. If in Prime mode prior to donor/patient connection, convert from a dual-needle to a single-needle procedure by using the MENU ON/OFF key as follows:

a. Press MENU ON/OFF key.

> 1 = Data Entry, 2 = Pressure Display, 3 = CCM,
> 4 = Air Remove, 5 = Strobe, 6 = Config., 7 = SN.

b. Press 7 to select single-needle conversion.

> Press 1 to convert this run to a
> single needle procedure.

(Enter LED is off.)

c. Press 1 to tell the system to display the necessary messages for conversion from a dual-needle procedure to a single-needle procedure at the appropriate time during the current procedure.

The following message appears:

> Single needle accepted. Conversion to
> SN will occur after Prime.

Priming continues normally until the time comes to connect the donor or patient, at which point the following message displays:

Operator Action | **System Action**

h. Open white return pinch clamp near return line connection to "Y" connector. Allow saline to fill luer lock connection and "Y" arm by gravity. Close white return pinch clamp.

i. Open white access pinch clamp near access line connection to "Y" connector. Allow saline to fill luer lock connection, "Y" arm, and needle by gravity. Close white access pinch clamp.

j. Press CONTINUE key.

For Platelet procedures, the following message will display:

Reconnect donor.	
Start return saline drip.	CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- 1800 rpm
Waste Valve	-- Unchanged
Plasma Valve	-- Unchanged
Collect Valve	-- Unchanged
RBC Line Valve	-- Closed
Return Line Valve	-- Closed

For TPE procedures, the following message will display:

Reconnect patient.	
Start return saline drip.	CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- 1800 rpm
Waste Valve	-- Unchanged
Plasma Valve	-- Unchanged
Collect Valve	-- Unchanged
RBC Line Valve	-- Closed
Return Line Valve	-- Closed

k. To connect the donor/patient:

1) Close roller clamps on access and return saline lines. Close white pinch clamps on access and return lines.

2) Perform venipuncture at needle site.

3) Open roller clamp and white pinch clamp on access saline line to provide a saline drip to keep the access/return needle open.

Operator Action	System Action
f) Place the bag's tubes on either side of the bag alignment block.	
3) Using aseptic technique, connect the single-needle bag to the Platelet or TPE blood tubing set:	
a) Place a clamp on each side of the male/female luer lock connector (above return air chamber) before continuing with Step b). (See Figure 1-8 for Platelet procedures and Figure 1-9 for TPE procedures.)	
b) Unscrew male/female luer lock connector.	
c) Remove protective cap from female port on single-needle bag and connect it to the male end of the disconnected male/female luer lock connector.	
d) Remove protective cap from male port on single-needle bag and connect it to the female end of the disconnected male/female luer lock connector.	
e) Secure but do not overtighten both connections.	
f) Remove clamps placed on either side of the luer lock connector in Step a).	
m. Note the number on the previous screen. Turn flow control handcrank on the Return Flow Controller (Figure 1-16) counterclockwise until the return flow indicator points to that number on the return flow scale (Figure 1-18).	
n. Press CONTINUE key.	

Operator Action	System Action

2. If in the Run mode, convert from a dual-needle to a single-needle procedure by following the steps below:

a. Press the MENU ON/OFF key.

> 1 = Data Entry, 2 = Pressure Display, 3 = CCM,
> 4 = Air Remove, 5 = Strobe, 6 = Config., 7 = SN.

b. Press the 7 key to select single-needle conversion.

> Press 1 to convert this run to a
> single needle procedure.

(Enter LED is off.)

c. Press the 1 key to confirm dual-needle to single-needle conversion.

> Clamp lines. Connect access and
> return lines to Y-manifold. CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- 1800 rpm
Waste Valve	-- Unchanged
Plasma Valve	-- Unchanged
Collect Valve	-- Unchanged
RBC Line Valve	-- Closed
Return Line Valve	-- Closed

d. Determine which needle will be removed and which needle will become the single access/return needle.

e. Close the needle clamp and white pinch clamp on line to the needle that will become the access/ return needle.

f. Start a *separate* saline drip at the access/return site to keep the access/return needle open.

g. Close the needle clamp and white pinch clamp on the line where the needle will be removed.

h. Remove the needle connected to the access site that will no longer be used.

i. Disconnect the needle from the blood tubing set and place it in an appropriate needle disposal container.

Operator Action	System Action

Reconnect donor.
Start return saline drip. CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- 1800 rpm
Waste Valve	-- Unchanged
Plasma Valve	-- Unchanged
Collect Valve	-- Unchanged
RBC Line Valve	-- Closed
Return Line Valve	-- Closed

For TPE procedures, the following message will display:

Reconnect patient.
Start return saline drip. CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- 1800 rpm
Waste Valve	-- Unchanged
Plasma Valve	-- Unchanged
Collect Valve	-- Unchanged
RBC Line Valve	-- Closed
Return Line Valve	-- Closed

o. To connect the donor/patient:

1) Clamp the access/return needle and remove separate saline drip to access/return site.

2) Remove protective cap from male port on the "Y" connector and connect that port to the access/return needle.

3) Secure but do not overtighten that connection.

4) Open white pinch clamp on access line and open clamp on needle line. Adjust the access saline roller clamp to provide a saline drip to keep the access/return needle open.

p. Install single-needle bag as follows:

NOTE
The single-needle bag is symmetrical and may be loaded with either side up.

Operator Action	System Action

4) Using aseptic technique, connect the single-needle bag to the Platelet or TPE blood tubing set:

   a) Place a clamp on each side of the male/female luer lock connector (above return air chamber) before continuing with Step b). (See Figure 1-8 for Platelet procedures and Figure 1-9 for TPE procedures.)

   b) Unscrew male/female luer lock connector.

   c) Remove protective cap from female port on single-needle bag and connect it to the male end of the disconnected male/female luer lock connector.

   d) Remove protective cap from male port on single-needle bag and connect it to the female end of the disconnected male/female luer lock connector.

   e) Secure but do not overtighten both connections.

   f) Remove clamps placed on either side of luer lock in Step a).

q. Note the number in the previous screen. Turn flow control handcrank on the Return Flow Controller (Figure 1-16) clockwise until the return flow indicator points to that number on the return flow scale (Figure 1-18).

r. Press CONTINUE key.

> Close access and return saline. Open access and return line clamps. CONTINUE.

All Pumps	-- Stopped
Centrifuge	-- 1800 rpm
Waste Valve	-- Unchanged
Plasma Valve	-- Unchanged
Collect Valve	-- Unchanged
RBC Line Valve	-- Closed
Return Line Valve	-- Closed

s. Close roller clamps on access and return saline lines.

MANUAL OVERRIDE OF CENTRIFUGE COVER AND DOOR LATCHES (Requires Small Screwdriver)

When there is a prolonged power failure or a system failure that does not allow the Spectra power to be turned on, the centrifuge cover and door can be opened by performing the following procedure:

Action	Explanation
1a. *For Spectra systems produced prior to September 1, 1990:* Locate small hole in each side of Spectra frame approximately 3 inches below "COBE Spectra" logo. (See left side of Figure 12-1.)	

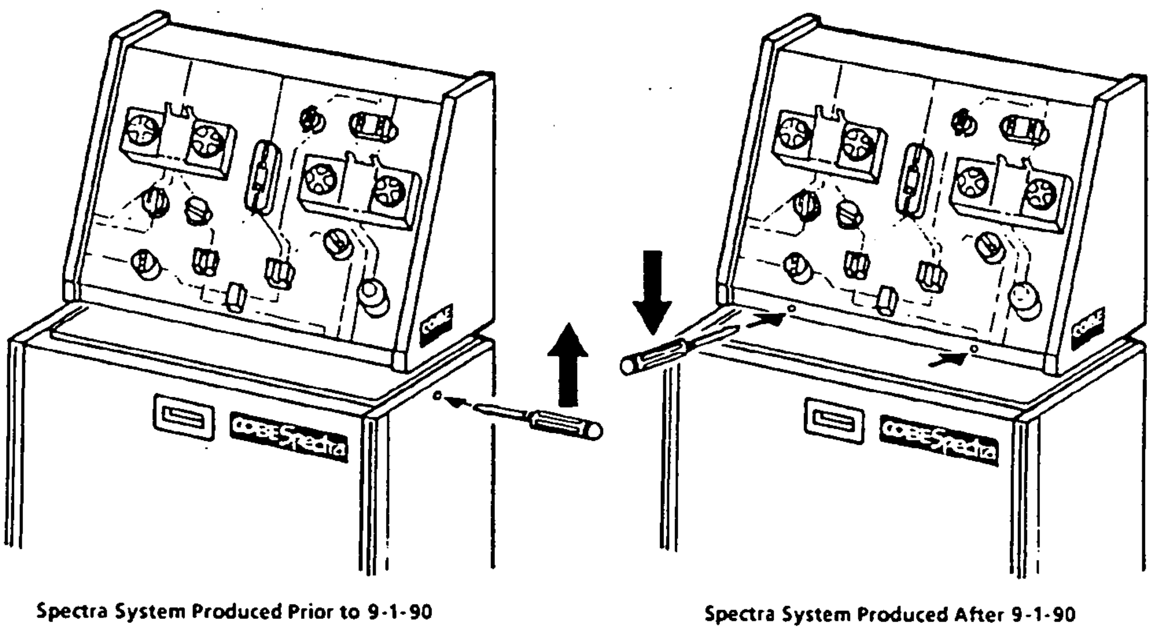

Figure 12-1. Spectra Cover and Door Latch Holes

Action	Explanation
1b. *For Spectra systems produced after September 1, 1990:* Locate the two small holes below the system's front panel. (See right side of Figure 12-1.) You will probably need to lean over to see the holes because the front panel extends over them.	

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MANUAL RINSEBACK PROCEDURE (Requires Blade Screwdriver)

If it is determined that the blood should be manually returned to the donor/patient, do the following:

Action	Explanation
1. Turn Spectra system's power switch off.	
2a. *For dual-needle procedures:* Close white pinch clamp on access needle line, and disconnect access needle.	
2b. *For single-needle procedures:* Clamp access line.	

> **WARNING**
> To avoid inadvertent removal of additional blood from donor/patient or return of fluids to donor/patient, ensure access is disconnected before starting manual rinseback. For single-needle procedures, ensure access line is clamped.

Action	Explanation
3. Use screwdriver to open waste valve.	This will relieve pressure from centrifuge.
4. Set valves to the following positions:	Use screwdriver in slot on top of valve.

Waste	-- Closed
Return	-- Open
RBC	-- Open
Plasma	-- Return
Collect	-- Collect

5. Remove tubing from return line valve.

6. Open access saline roller clamp all the way.

> **WARNING**
> **Alarm system is inactivated with power off. Watch for air in the return line while returning blood to donor/ patient. If you see air is seen in line, discontinue manual rinseback immediately.**

MANUAL SPILLOVER RECOVERY PROCEDURE FOR DUAL-NEEDLE PLATELET PROCEDURES

It will be necessary to perform this procedure if red cells have entered the second stage of a dual-stage channel for any one of the following reasons:

- Centrifuge is stopped (for example, because of an alarm).
- Donor/patient parameters are entered incorrectly.
- Plasma pump flow rates were incorrectly set during Manual operation.

IMPORTANT NOTE
A spillover procedure will be performed automatically by the Spectra system if spillover is detected by the CCM.

Action	Explanation
1. Press PAUSE key to stop pumps.	
2. If centrifuge is stopped:	
a. Close white return line clamp and open roller clamp on return saline line.	If centrifuge is brought up to speed while open to donor return, system will draw blood from return needle. It will not be anticoagulated blood.
b. Bring centrifuge up to speed.	
c. Once centrifuge is up to speed, close roller clamp on return saline line and open white return line clamp.	
3. Press MANUAL key.	
4. Press CLEAR key to return to flow screen.	May take multiple presses of CLEAR key.
5. Use VALVE key selections to put collect valve in return position.	
6. Press CLEAR key to return to flow screen.	May take multiple presses of CLEAR key.
7. Set collect pump flow rate to the following: (Collect flow rate + plasma flow rate) – 2 ml/min	
8. Set plasma pump flow rate to zero.	

MANUAL SPILLOVER RECOVERY PROCEDURE FOR SINGLE-NEEDLE PLATELET PROCEDURES

It will be necessary to perform this procedure if red cells have entered the second stage of a dual-stage channel for any one of the following reasons:

- Centrifuge is stopped (for example because of an alarm).
- Donor/patient parameters are entered incorrectly.
- Plasma pump flow rates were incorrectly set during Manual operation.

IMPORTANT NOTE
A spillover procedure will be performed automatically by the Spectra system if spillover is detected by the CCM.

Action	Explanation
1. Press PAUSE key to stop pumps.	
2. If centrifuge is stopped:	
a. Close white needle clamp and open roller clamp on access saline line.	If centrifuge is brought up to speed while open to donor access/return, system will draw blood from access/return needle. It will not be anticoagulated blood.
b. Bring centrifuge up to speed.	
c. Once centrifuge is up to speed, close roller clamp on access saline line and open white needle clamp.	
3. Press MANUAL key.	
4. Press CLEAR key to return to flow screen.	May take multiple presses of CLEAR key.
5. Use slide clamps to close lines to both collect and plasma bags.	
6. Use VALVE key selections to put collect valve in return position.	
7. Press CLEAR key to return to flow screen.	May take multiple presses of CLEAR key.
8. Set collect pump flow rate to the following:	
(Collect flow rate + plasma flow rate) – 4 ml/min	

MANUAL SPILLOVER RECOVERY PROCEDURE FOR SINGLE-NEEDLE PLATELET PROCEDURES (Continued)

- Raise hematocrit value by 2, and press ENTER.
- Press MENU ON/OFF key.

b. Press MANUAL key to return to Automatic operation.

c. Use VALVE key selections to move collect valve to collect position.

For single-needle procedures, moving the collect valve to the collect position will be delayed until the end of the next single-needle return phase. You will receive the following message informing you of that fact: "Valve will be moved at end of return cycle."

13. Move the slide clamps to both the collect and plasma bags to the open position.

RED CELL ACCUMULATION IN TPE CHANNEL

If the red cell/plasma interface reaches the center of the channel (see Figure 12-2), perform the following procedure:

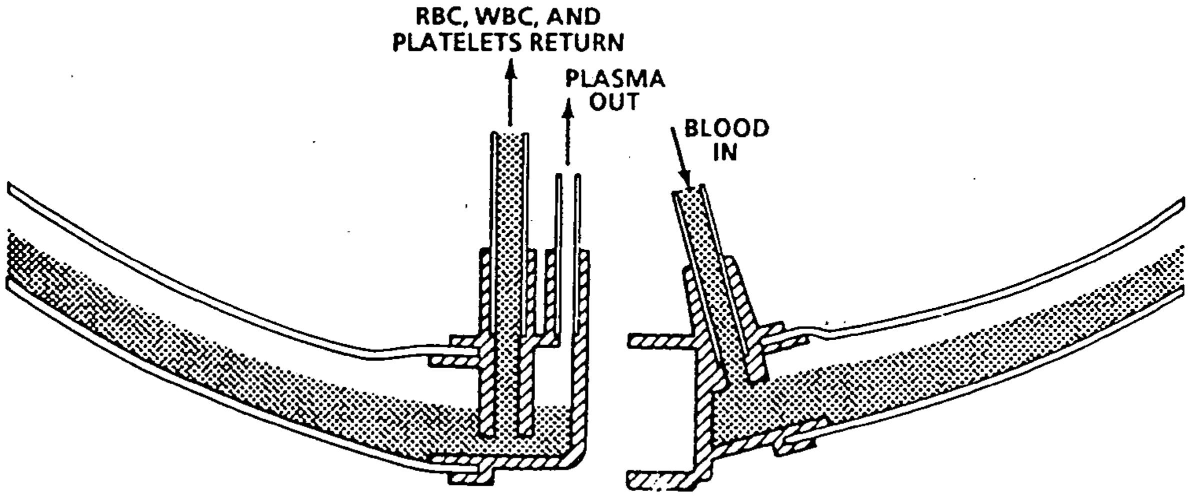

Figure 12-2. Red Cell Accumulation In TPE Channel

Action	Explanation
1. Press PAUSE KEY.	
2. Increase entered patient hematocrit.	Prevents red cell accumulation from recurring.
a. Press MENU ON/OFF key.	
b. Press 1 key to select "Data Entry."	
c, Press 2 key to select "Change patient information."	
d. Press 4 key to select "HCT."	
e. Raise hematocrit value by 3, and press ENTER.	
f. Press MENU ON/OFF key.	
3. Press MANUAL key to place the system in Manual operation.	
4. Set plasma pump flow rate to zero.	
5. Set replace pump flow rate to zero.	

RED CELL ACCUMULATION IN RBCX CHANNEL

If the red cell/plasma interface reaches the center of the channel (see Figure 12-4), perform the following procedure:

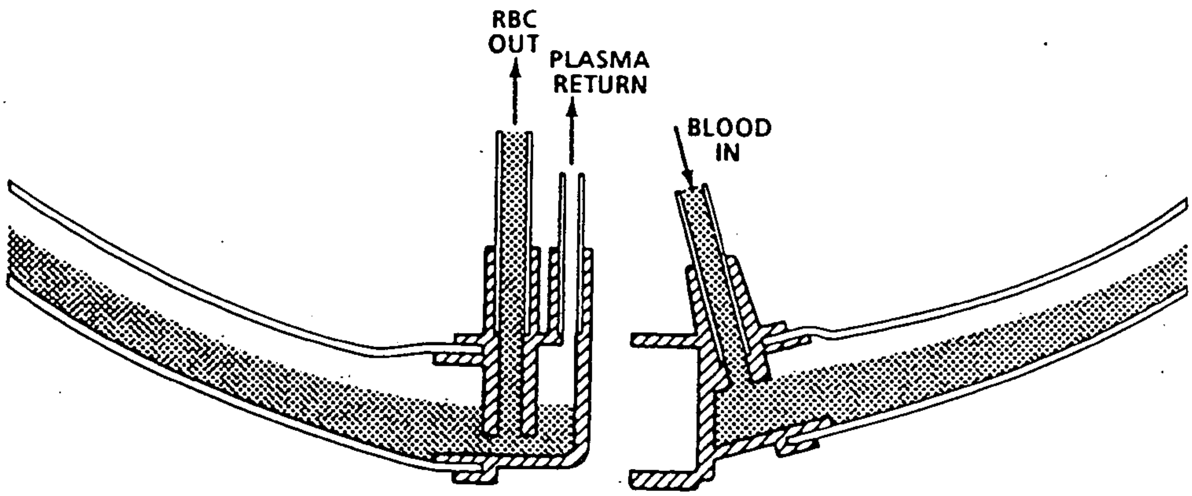

Figure 12-4. Red Cell Accumulation in RBCX Channel

Action	Explanation
1. Press PAUSE KEY.	
2. Increase entered patient hematocrit.	Prevents red cell accumulation from recurring.
a. Press MENU ON/FF key.	
b. Press 1 key to select "Data Entry."	
c. Press 2 key to select "Change patient information."	
d. Press 4 key to select "HCT."	
e. Raise hematocrit value by 3, and press ENTER.	
f. Press MENU ON/OFF key.	
3. If, after 10 minutes, the interface is still at or above the center of the channel, repeat Step 2.	

RETURN PRESSURE SENSOR LOADING WITH FLUID IN SET

It may be necessary to perform this procedure when there is fluid in the blood tubing set during Prime or Run modes because the return pressure sensor has either not been positioned correctly or the sensor has been accidentally disengaged from the return pressure sensor housing.

The diaphragm in the return pressure sensor must be returned to neutral position so the transducer in the housing can monitor return pressure accurately.

Action	Explanation
1. Press PAUSE key to place Spectra system into Pause mode and then clamp line immediately above return pressure sensor.	
2. Remove return pressure sensor from housing.	
3. a. *For All Procedures Except Single-Needle ELP:* Close return line clamp.	
b. *For Single-Needle ELP Procedures Only:* Open return line valve if necessary, and wait for single-needle bag to empty. Then, if in Run mode, close needle clamp.	
4. a. *For All Procedures Except Single-Needle ELP:* Open return line valve.	
b. *For Single-Needle ELP Procedures Only:* Open access line clamp.	
5. a. *For All Procedures Except Single-Needle ELP:* Open return saline roller clamp.	
b.. *For Single-Needle ELP Procedures Only:* Open access saline roller clamp.	
6. Lower saline container until fluid level in container is slightly below that in the return pressure sensor.	
7. Wait for a few seconds to allow diaphragm in sensor to center.	

SINGLE NEEDLE TO DUAL NEEDLE BACKOUT PROCEDURE

If you begin a Platelet or TPE procedure as a single-needle operation, you can change that procedure to a dual-needle operation up to the time that the Prime mode is completed. To perform this single needle to dual needle backout, follow these steps:

Operator Action	System Action
1. Press MENU ON/OFF key.	1 = Data Entry, 2 = Pressure Display, 3 = CCM, 4 = Air Remove, 5 = Strobe, 6 = Config., 7 = SN.
2. Press 7 key to select single needle.	The following message is displayed because you previously told the Spectra system that you wanted to run a single-needle procedure but the actual single-needle steps have not yet begun. Single needle conversion pending. Press 1 to cancel SN. (ENTER LED is off.)
3. Press 1 to tell the Spectra system to cancel your previously requested dual-needle to single-needle conversion.	

13-Maintenance

SECTION 13 - MAINTENANCE

OPERATOR MAINTENANCE OF SPECTRA™ APHERESIS SYSTEM

The procedures in this section are to be performed by an operator or technician trained in the use of the COBE Spectra™ Apheresis System. The only tool required is a flat blade screwdriver.

CAUTION

Due to the possible exposure to hepatitis virus, human immunodeficiency virus, and other infectious agents in the handling of extracorporeal blood circuits, adequate precautions should be taken at all times to prevent exposure to and transmission of such agents.

AFTER EVERY PROCEDURE OR AS NECESSARY

CLEANING

Use a mild detergent to clean spill deposits (that is, blood, saline, etc.) from the surface of the Spectra system.

To clean the pump housings and rotors, perform the following:

1. Grasp the top of the rotor, push it in, and twist it counterclockwise to remove it from the housing.
2. After cleaning the housing and bottom of the rotor, align the rotor with the housing, push the rotor in, and turn it clockwise.
3. Place the cloth, etc., used to clean the system in an appropriate biohazard disposal container.

DISINFECTING

To disinfect the surfaces of the Spectra system, use a 1/4% bleach solution. Commercial household bleach (5-1/4% to 6%) when diluted 1 part bleach with 18 parts water will give approximately 1/4% sodium hypochlorite bleach solution.

NOTE

Using a stronger bleach solution than is recommended can cause damage or discoloration.

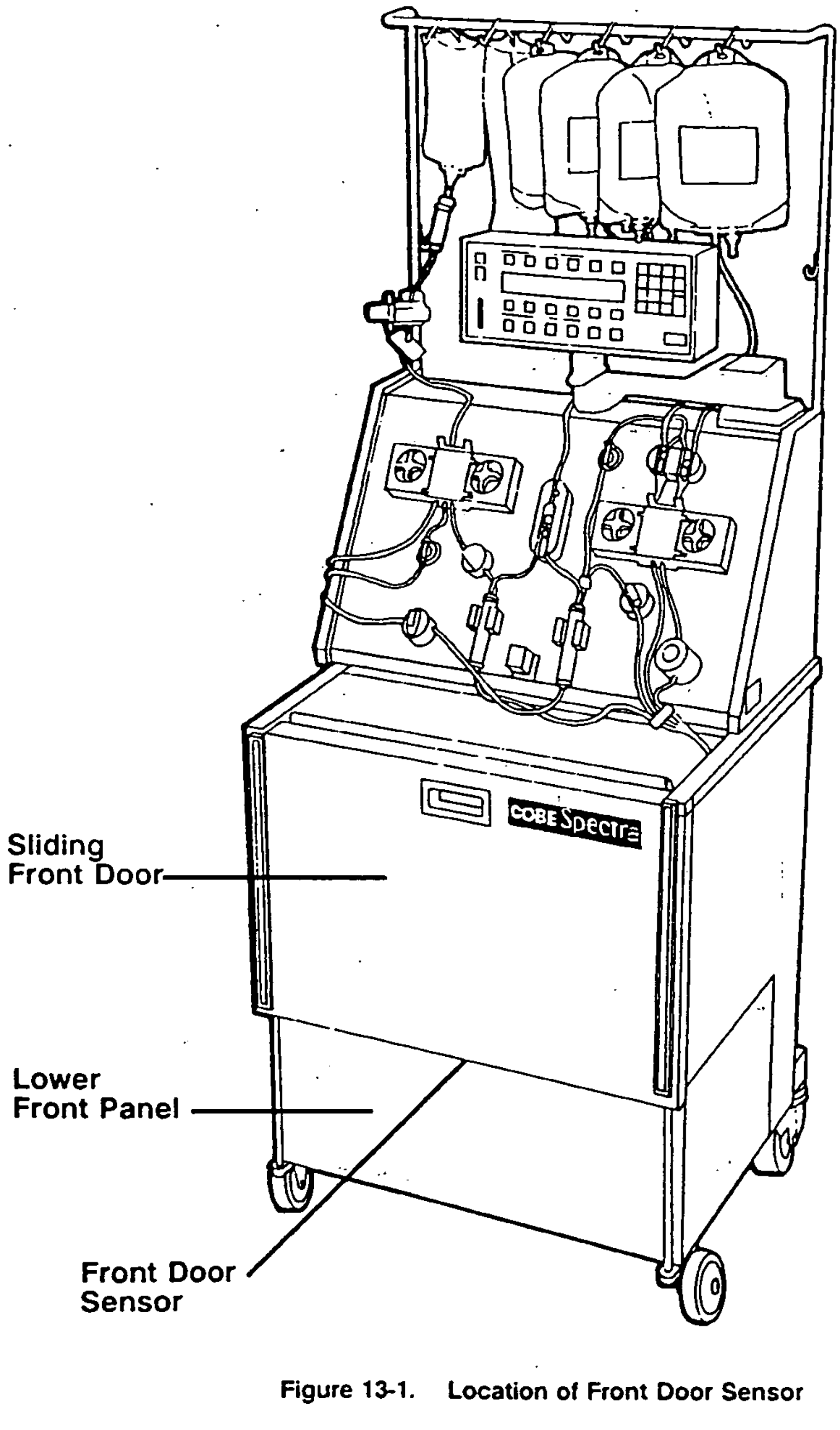

Figure 13-1. Location of Front Door Sensor

- AC level detector
- Leak detector
- Optical door switches
- Door interlock

NOTE

If any check is not passed satisfactorily, notify a qualified service technician or COBE Customer Engineering Representative.

The following materials are needed to perform the checkout procedure:

- Dual-stage channel filler
- Dual-Needle ELP blood tubing set
- Two variable tubing occluders (Harvard clamps)
- Saline: 1000-ml bag and 500-ml bag
- Clamps or hemostats

Loading and Priming:

1. Install the Dual-Needle ELP blood tubing set following the **SETTING UP ELP DISPOSABLES** procedure in SECTION 3A – DUAL-NEEDLE ELP OPERATION. **Do not install the lines in any of the valves except the return line valve.**

2. As the messages listed below are displayed, perform the steps they request you to follow:

   a. "Select set." Press 1 to select ELP set.

   b. If "Select: 1 = Single needle, 2 = Dual needle" appears, press 2 to select Dual needle.

   c. "Clamp access and return lines. Close both saline lines. Press CONTINUE."

   d. "Connect Platelet tubing set to fluid containers. Press CONTINUE."

   e. "Open access and return saline lines. Press CONTINUE to prime."

   f. Refer to the **ELP COLLECTION** section in SECTION 3A – DUAL-NEEDLE ELP OPERATION to follow Prime mode sequence.

   During the first "Testing sensors, valves, and pumps" step, the centrifuge pressure sensor, inlet waste valve, and plasma pump operations are verified. Since the valves are not loaded, the following alarm message should appear: "CENTRIFUGE PRESSURE ERROR!"

3. Load the lines in all the valves and press CONTINUE.

   a. Continue to refer to the **ELP COLLECTION** section in SECTION 3A – DUAL-NEEDLE ELP OPERATION to follow Prime mode sequence.

   b. "Prime access and return connections. Press CONTINUE."

   c. Use forceps to clamp AC line from the anticoagulant container below the AC pump.

   d. "Close access saline line. Clamp access line. Press CONTINUE to test AC ratio."

   e. "Testing AC ratio."

c. Use the occluder on the return line to increase the return pressure to the red alarm point. Refer to the pressure display to verify a pressure of about 400 ± 50 mmHg. Verify the alarm indicators and automatic system action:

- Message = "RETURN PRESSURE HIGH! Check return line and needle."
- Alarm LED = red
- Audible alarm = chime
- Automatic system action = pumps stop

2. Return Line Valve

Manually push on the return line valve and verify that the following alarm message is displayed: "RETURN VALVE POSITION ERROR!"

3. Inlet Air Detector

a. Remove the inlet air chamber from the inlet air detector. Verify that the following alarm message is displayed: "AIR IN INLET CHAMBER! Hold 1 key until air is removed."

b. Replace the inlet air chamber in the detector, and press the CONTINUE key.

4. Return Air Detector

a. Remove the return air chamber from the return air detector. Verify that the following alarm message is displayed: "AIR IN RETURN CHAMBER! Hold 2 key until air is removed."

b. Replace the return air chamber in the detector.

c. Press and hold the 2 key. Verify that the system stops the air remove function in 30 seconds.

5. AC Level Detector

a. Remove the AC line from the AC level detector and verify that the "OUT OF ANTICOAGULANT!" message is displayed.

b. Verify that the CONTINUE key can be used to temporarily override this alarm for up to 10 seconds maximum. Replace the tubing in the AC level detector.

6. Leak Detector Test

a. Using Manual operation, command a speed of zero in the centrifuge rpm display by pressing SPIN RPM, 0, and ENTER. Open the centrifuge cover and door. Apply a slightly moist cloth over the leak detector.

b. Close the door and cover, enter a centrifuge rpm of 2400, and verify that the "FLUID LEAK IN CENTRIFUGE!" alarm message is displayed.

c. Wipe all moisture off the leak detector, the basin, and the centrifuge before resuming the checkout.

7. Cover Interlock

a. Close the centrifuge door and cover, return the centrifuge speed to 2400 rpm, and verify that the door and cover are locked closed.

DISINFECTING

To disinfect the Return Flow Controller, use a 1/4% bleach solution. Commercial household bleach (5-1/4% to 6%) when diluted 1 part bleach to 18 parts water will give approximately 1/4% sodium hypochlorite bleach solution. This solution should be used to wipe blood-product spills from the Return Flow Controller.

To disinfect spills that cannot readily be wiped up, the Return Flow Controller may be immersed for 5 minutes in a sink containing the 18:1 bleach solution, immediately rinsed, and then dried. While immersed, the Return Flow Controller should be cranked through one full up/down cycle. This will ensure that all parts of the Return Flow Controller's internal mechanism are exposed to the bleach.

The Return Flow Controller's materials are all resistant to corrosion from tap water and most cleaning solutions. Consequently, drying all of the internal parts is not critical.

NOTE

Using a stronger bleach solution than is recommended can cause damage or discoloration.

TECHNICIAN MAINTENANCE FOR SPECTRA™ APHERESIS SYSTEM

The procedures listed below should be performed at 6-month intervals by qualified service technicians only. Refer to the *COBE Spectra Service Manual* for functional descriptions and information on performing the following procedures:

1. Power Supply Check
    - ac Line Voltage
    - 60 Vdc
    - 24 Vdc
    - ± 15 Vdc
    - 5 Vdc
2. Valve Function Check
3. Centrifuge Cover Interlock Check
4. Leak Detector Alarm Check
5. Vibration Detector Alarm Check
6. Pressure Sensors (Access, Return, Centrifuge)
    - Calibration
    - Alarm Function Test
7. RBC Detector Calibration
8. Collect Concentration Monitor Calibration
9. Pump Alignment and Occlusion Test

SECTION 14 - SPECIFICATIONS

SPECIFICATIONS

PHYSICAL

Characteristics	Performance	Conditions
Weight	177 kg (389 lb)	
Physical dimensions	Height: 148 cm (58 inches) (178 cm [70 inches] with IV pole) Width: 70 cm (27.6 inches) Depth: 71 cm (27.9 inches)	
Floor space required	4970 cm^2 (770 square inches) maximum	
Case material and finish	Painted steel, aluminum, and plastic	

ENVIRONMENTAL

Characteristics	Performance	Conditions
Ambient operating temperature	18°C to 27.5°C (64°F to 81°F) to maintain maximum blood temperature below 42°C (107°F)	rpm = 2400 Minimum blood flow = 25 ml/min
Ambient operating humidity	8% to 80% RH, noncondensing	
Storage temperature	0°C to 60°C (32°F to 140°F)	
Fluid spillage	Unit shall not be rendered unsafe by spillage over the top	
Restrictions	Not to be used in an explosive atmosphere	
Cleanability	Unit will not be damaged by 1/4% sodium hypochlorite dilute bleach; pump rotors are removable; channel leaks are contained within centrifuge basin	

AC POWER

Characteristics	Performance	Conditions
Line voltage	100 ± 10% Vac, 47 to 63 Hz 115 ± 10% Vac, 47 to 63 Hz 220 ± 10% Vac, 47 to 63 Hz 240 ± 10% Vac, 47 to 63 Hz	
Input line current	8 A maximum RMS at 100/115 Vac 4 A maximum RMS at 220/240 Vac	Circuit breaker overcurrent protection

ELECTRICAL SAFETY

Characteristics	Performance	Conditions
Electrical safety standards	115 V units meet or exceed "Recommended AAMI safety standards for Electromechanical apparatus" under the classification "Non-Isolated apparatus" as set forth by the Association for the Advancement of Medical Instru-mentation	
AC leakage current	50 microamperes maximum RMS, 115 Vac – North America 100 microamperes maximum RMS, 100/220/240 Vac	

SAFETY CERTIFICATIONS

Certification	Status	Model Certified
Canadian Standards Association C22.2, No. 125-M1984	Certified File #LR 29798	950000-000 950000-004
Underwriters Laboratories UL 544	Listed File #E 97083	950000-000 950000-004 950000-007
British Standards Institution BS 5724.1/IEC 601.1	Test Certificates Issued No. 146266 146266/1	950000-001 950000-002 950000-003 950000-005 950000-006 950000-008
TÜV Bayern (Germany)	Med GV Nr.: 02/M-069/89	950000-005
Ministry of Health (France)	Certification Nos.: 1369-88-5 890214 for Platelet-pheresis 1369-88-5 890525 for TPE	950000-003
Ministry of Health (Japan) JIS T 1001, 1002, 1003, 1004, 1005, 1021, and other requirements	Certified	950000-007

FLOW RATES AND SPEEDS

Characteristics	Performance	Conditions
AC pump flow rate range	1.0 to 12 ml/min	0 to +50 mmHg inlet pressure 0 to −250 mmHg outlet pressure Tubing ID: 0.113 Automatic loading/unloading
AC pump flow rate accuracy	± 6% of display value or ± 0.2 ml/min, whichever is greater	
Inlet pump flow rate range	20 to 150 ml/min*	0 to −250 mmHg inlet pressure 0 to +400 mmHg outlet pressure Tubing ID: 0.113 Automatic loading/unloading
Inlet pump flow rate accuracy	± 6% of display value or ± 0.4 ml/min, whichever is greater	
Plasma pump flow rate range	2 to 100 ml/min*	0 to +400 mmHg inlet pressure 0 to +400 mmHg outlet pressure Tubing ID: 0.113 Automatic loading/unloading
Plasma pump flow rate accuracy	± 6% of display value or ± 0.4 ml/min, whichever is greater	
Plasma/red cell exchange fluid balance range	75% to 150% of plasma removed	Plasma and collect/replace pumps: 2 to 70 ml/min flow rate Inlet pump: 20 to 120 ml/min flow rate AC ratio: 9:1 to 20:1 Maximum return pressure: 350 mmHg
Plasma/red cell exchange fluid balance accuracy	85% to 120% fluid balance: ± 8% of command balance 120% to 150% fluid balance: ± 10% of command balance	
Collect/replace pump flow rate range	1 to 100 ml/min*	0 to +400 mmHg inlet pressure 0 to +400 mmHg outlet pressure Tubing ID: 0.113 Automatic loading/unloading
Collect/replace pump flow rate accuracy	± 6% of display value or ± 0.2 ml/min, whichever is greater	

* Flow rates can be entered that are outside the performance specification described above (inlet pump = 0 to 150 ml/min; plasma pump = 0 to 150 ml/min; collect/replace pump = 0 to 150 ml/min). However, COBE makes no accuracy claim for values outside the specified performance range for each pump.

RETURN FLOW CONTROLLER

Characteristics	Performance	Conditions
Weight	3.4 kg (7.5 lb)	Empty Bag
Maximum Return Flow Rate – Over 1 Cycle	200 ml/min	400 mmHg Peak 17-gauge needle Stroke Volume: 50 ml

BLOOD TUBING SETS

Characteristics	Performance	Conditions
ELP/platelet blood set volume	Approximately 131 ml	Equivalent volume of donor/patient blood based on red blood cells
TPE/RBCX blood set volume	Approximately 170 ml	
WBC blood volume	Approximately 284 ml	
Single-needle additional extra-corporeal blood volume (approx)	SN-ELP and SN-Platelet: 81 ml maximum at inlet flow rate = 50 ml/min SN-TPE: 84 ml maximum at inlet flow rate = 60 ml/min	• Equivalent volume of donor/patient blood based on red blood cells with inlet:AC ratio = 10:1 • Reached at end of draw phase. Drops to about 13 ml after return
ELP/platelet residual volume	Approximately 19 ml	Equivalent to donor/patient hematocrit
TPE/RBCX residual volume	Approximately 37 ml	
WBC residual volume	Approximately 60 ml	
Single-needle additional residual volume	SN-ELP, SN-Platelet, and SN-TPE: approximately 4 ml	Donor/patient equivalent blood volume

CENTRIFUGE

Characteristics	Performance	Conditions
Centrifuge speed range	400 to 2400 rpm	
Centrifuge speed accuracy	± 5%	
Maximum G-forces developed in channel	910 G = dual-stage channel 930 G = single-stage channel	At 2400 rpm with single-stage channel

SAFETY

Characteristics	Performance	Conditions
Alarms	Audio alarm (mutable), red flashing light, yellow light, display prompts	
Shutdown conditions	Pumps shut down automatically under red alarm conditions. Centrifuge shuts down if pumps stopped > 10 min.	Shut down may be initiated using STOP SPIN key.

SENSORS

Access Pressure Sensor:

Characteristics	Performance	Conditions
Operating range	−300 to +50 mmHg	
Default alarm pressure	−250 ± 30 mmHg and lower default	
Operator-adjusted alarm pressure	−50 to −250 mmHg ± 30 mmHg	For current run only
Accuracy	± 12% of reading or ± 20 mmHg, whichever is greater	

Return Pressure Sensor:

Characteristics	Performance	Conditions
Operating range	−50 to 450 mmHg	
Default alarm pressure	400 ± 48 mmHg	
Operator-adjusted alarm pressure	50 to 400 mmHg ± 48mmHg	For current run only. Single-needle runs are not adjustable at 400 ± 48 mmHg.
Accuracy	± 12% of reading or ± 20 mmHg, whichever is greater	

Centrifuge Pressure Sensor:

Characteristics	Performance	Conditions
Operating range	400 to 1200 mmHg	
Alarm pressure	1200 mmHg	

Air Detectors (Inlet and Return Air Chambers):

Characteristics	Performance	Conditions
Minimum air volume sensed	• 5 to 10 ml (1/4 to 1/2 chamber volume) at 120 ml/min • Detects foam condition • Air chamber filter prevents bubbles (200 micron or larger) from entering line at bottom of air chamber. •Will alarm when sensors are unloaded	
Time to alarm	• When air is detected, stops pumps before air enters line at bottom of air chamber • Auto self-test feature on return air chamber detector	

Anticoagulant Level Detector:

Characteristics	Performance	Conditions
Time to alarm	• 2 seconds maximum after sensing air • Will alarm when sensor is unloaded	

Collect Concentration Monitor:

Characteristics	Performance	Conditions
Range	0 to 5 × 10^6 platelets/ul	
RBC spillover detector	RBC levels greater than . % hematocrit	

RBC Detector:

Characteristics	Performance	Conditions
Divert trip point	3% to 30% hematocrit	

AC PUMP ALARM RESPONSES

AC Pump Out-of-Range Alarm:

Characteristics	Performance	Conditions
Detection method	AC pump equipped with Hall-effect sensor to measure pump flow rate as pump rotations. Measured pump flow rate is compared to commanded pump flow rate. If measured error is out of range for delay time, alarm is generated	Pump flow rate > 4 ml/min
Accuracy	Measured flow rate: –25% to +60% of commanded flow rate	
Delay time	Measured error remains outside range limits for 31 seconds.	

AC Pump Runaway Alarm:

Characteristics	Performance	Conditions
Detection method	AC pump equipped with Hall-effect sensor to measure pump flow rate as pump rotations. If system is Paused and measured flow rate is not zero, alarm is generated.	
Accuracy	Less than 2 revolutions of pump (approximately 2 ml) are allowed after Paused condition.	
Delay time	Less than 1/2 second from time second revolution is detected until alarm is generated	

Maximum AC Flow Alarm (Dual-Needle Only):

Characteristics	Performance	Conditions
Detection method	Commanded AC flow rate is checked twice against computer (ROM) based absolute limit of 12.0 ml/min – first against an absolute limit, second against absolute limit inverted. If either test shows commanded flow rate greater than absolute limit, alarm is generated.	Does not check during some priming steps
Accuracy	Alarm will be generated at 12.1 ml/min or greater	
Delay time	1/4 second from time pump flow rate command is received until alarm is generated.	

Maximum AC Volume Alarm :

Characteristics	Performance	Conditions
Detection method	AC pump equipped with Hall-effect sensor to measure pump flow rate as pump rotations. If pump rotates more than an absolute limit of 296 times in 20 min (corresponding to 250 ml of AC), an alarm is generated.	Does not check during some priming steps
Accuracy	Plus or minus one pump rotation	
Delay time	1/4 second from time 256th rotation is counted until alarm is generated	

APPENDIX A

KEYBOARD SELECTIONS

A menu is a selection message on the Spectra display screen, which gives you an opportunity to make various choices when operating the COBE Spectra™ Apheresis System. You make these selections by pressing a key on the keypad on the Spectra control panel. See Figure 1-15 in SECTION 1 – INTRODUCTION for a description of the Spectra control panel. To access the various selection messages, press the VALVE, CHANGE MODE, or MENU ON/OFF key. Following are explanations of the possible keyboard selections:

VALVE KEY

Use the VALVE key to display selection messages and move individual valves. When you make a selection, the message stays on the screen, allowing you to choose another valve to move. The message will display for 30 seconds unless the VALVE key is pressed again or the CLEAR key is pressed from the *first valve selection message*. Pressing the CHANGE MODE or MENU ON/OFF key will also remove the message. For descriptions of the five Spectra valves and explanations of their functions, see the **Front Panel** subsection of the **SYSTEM COMPONENTS** section and the **System Components** subsection of the **FUNCTIONAL DESCRIPTION** section of SECTION 1 – INTRODUCTION.

The VALVE key selection messages are described in the following pages. The first message lets you select the valve to move. The second-level selection message lets you choose to what position to move the valve. The ENTER LED will flash for all of these selection messages, showing that ENTER may also be used to remove the message.

FIRST VALVE SELECTION MESSAGE

```
1 = Return, 2 = RBC, 3 = Waste, 4 = Collect,
5 = Plasma, 6 = All valves.
```

- Press 1 = displays *return line valve selection message*
- Press 2 = displays *RBC line valve selection message*
- Press 3 = displays *waste divert valve selection message*
- Press 4 = displays *collect/replace valve selection message*
- Press 5 = displays *plasma valve selection message*
- Press 6 = displays *all valves selection message*
- Press CLEAR or ENTER = removes selection message from screen

1 = Return Line Valve Selection Message

```
Return Line Valve (now ______):
1 = Close, 2 = Open.
```

The blank in the selection message will contain "Open" or "Closed" depending on the return line valve position when this message is displayed.

- Press 1 = closes return line valve
- Press 2 = opens return line valve
- Press CLEAR = redisplays *first valve selection message*
- Press ENTER = removes selection message from screen

2 = RBC Line Valve Selection Message

```
RBC Line Valve (now ______):
1 = Close, 2 = Open.
```

The blank in the selection message will contain "Open" or "Closed" depending upon the position of the RBC line valve when this message is displayed.

- Press 1 = closes RBC line valve
- Press 2 = opens RBC line valve
- Press CLEAR = redisplays *first valve selection message*
- Press ENTER = removes selection message from screen

3 = Waste Divert Valve Selection Message (See Figure A-1)

```
Waste: 1 = Inlet Divert, 2 = Return Divert,
3 = Close, 4 = Recirculate, 5 = Load.
```

	Waste Line	Inlet Waste	Return Waste
• Press 1 =	Open	Open	Closed
• Press 2 =	Open	Closed	Open
• Press 3 =	Closed	Open	Closed
• Press 4 =	Closed	Open	Open
• Press 5 =	Open	Open	Open

- Press CLEAR = redisplay *first valve selection message*
- Press ENTER = removes selection message from screen

4 = **Collect/Replace Valve Selection Message** (See Figure A-2)

Collect Valve (now _______): 1 = Collect, 2 = Return, 3 = Load.

The blank in the selection message will contain "Collecting," "Returning," or "Open" (Load position) depending upon the position of the collect/replace valve when this message is displayed.

- Press 1 = collected cells go to collect bag (valve pinches collect return line)
- Press 2 = collected cells are returned to donor/patient (valve pinches collect bag line)
- Press 3 = collect valve is open (center position) for loading tubing
- Press CLEAR = redisplays *first valve selection message*
- Press ENTER = removes selection message from screen

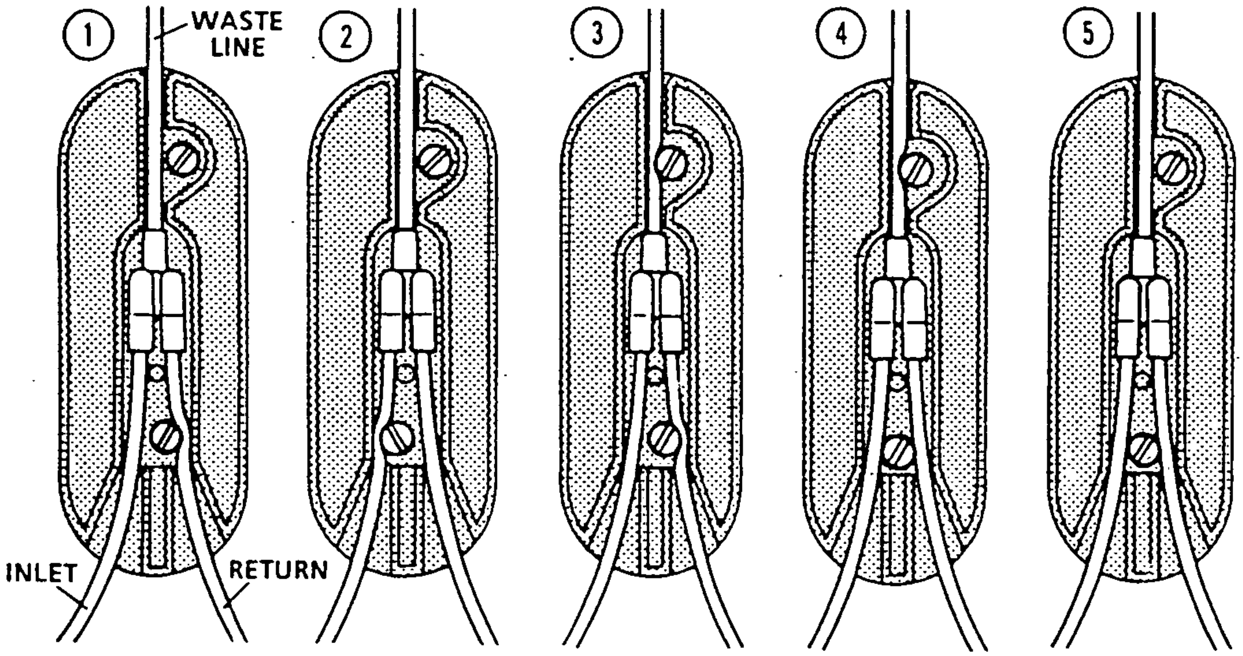

Figure A-1. Waste Divert Valve Positions

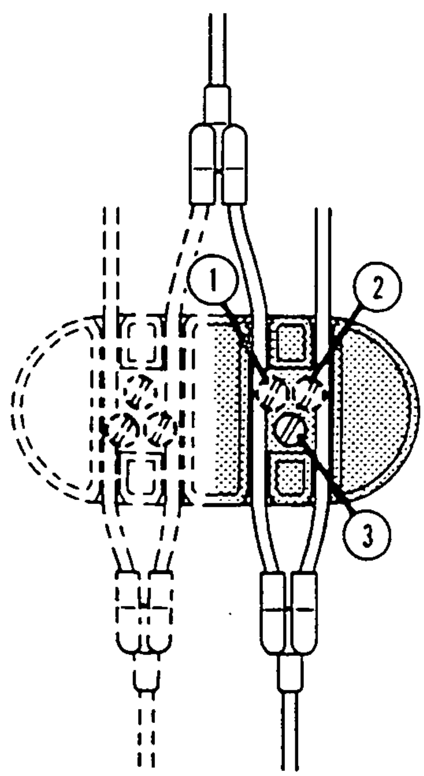

Figure A-2. Collect/Replace Valve Positions

5 = **Plasma/RBC Valve Selection Message** (See Figure A-3)

Plasma Valve (now ______): 1 = Collect, 2 = Return, 3 = Load.

The blank in the selection message will contain "Collecting," "Returning," or "Open" (Load position) depending upon the position of the plasma/RBC valve when this message is displayed.

- Press 1 = plasma goes to plasma collect bag (valve pinches plasma/RBC return line). For RBCX procedures, red blood cells go to RBC collect bag.
- Press 2 = plasma is returned to donor/patient (valve pinches plasma/RBC bag line). For RBCX procedures, red blood cells are returned to patient.
- Press 3 = plasma valve is open (center position) for loading tubing
- Press CLEAR = redisplays *first valve selection message*
- Press ENTER = removes selection message from screen

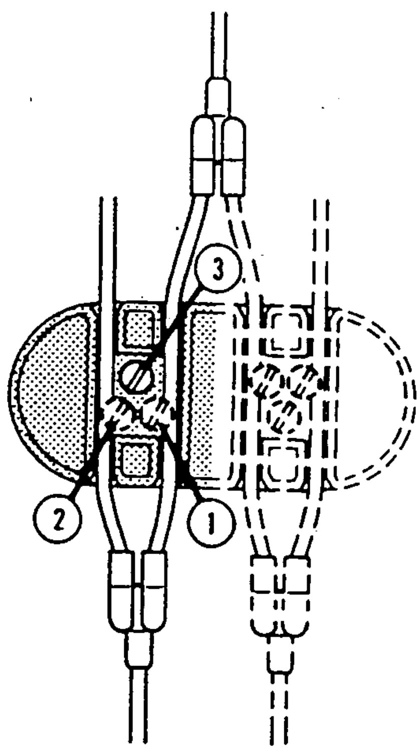

Figure A-3. Plasma Valve Positions

6 = All Valves Selection Message

1 = Close All Valves, 2 = Open All Valves.

- Press 1 = clamp these lines: return, RBC, waste bag, return waste, plasma bag, collect bag
- Press 2 = move all valves to open position for loading tubing
- Press CLEAR = redisplays *first valve selection message*
- Press ENTER = removes selection message from screen

VALID VALVE POSITION CHANGES

Either of the following two messages may be displayed after attempting to change valve positions when alarm conditions are present: "RETURN VALVE BAD - CANNOT DO AIR REMOVE!" or "VALVE HELD IN PLACE BY ALARM! Must clear alarm before moving valve." A third message - "INVALID VALVE MOTION!" - will be displayed after attempting to change a valve position when it is not allowed due to donor/patient safety concerns.

A fourth message - "VALVE WILL BE MOVED AT END OF RETURN CYCLE" - will be displayed when attempts are made to move collect valve or plasma valve during single-needle procedures in the Run mode when pressure is stored in the Return Flow Controller during a return cycle. The Spectra system will move the requested valve at the end of the return cycle after the pressure in the Return Flow Controller has decreased.

A fifth message - "VALVE MOTION CANCELED" - is displayed anytime the system cancels a requested valve motion because movement of that valve is inappropriate during that portion of the current procedure. See Table A-1 for valid valve position changes.

Table A-1. Valid Valve Position Changes

Mode (State)	Return Line Valve	RBC Line Valve	Waste Divert Valve	Plasma/RBC Valve	Collect/Replace Valve	
					TPE/RBCX Procedures	All Other Procedures
Preload	Yes	Yes	Yes	Yes	Yes	Yes
Load (Set Select, Single Needle, Set Return Flow Scale	Yes	Yes	Yes	Yes	Yes	Yes
Load (Close Clamps, Connect Fluids)	Yes	Yes	Yes	Yes	No	Yes
Prime to ReRun	Yes	Yes	Yes	Yes	No	Yes
Run	Yes	No	Yes	Yes, except Load position in Automatic mode*,**	No	Yes, except Load position in Automatic mode**
Rinseback (Clamp Access, Collecting)	Yes	Yes	Yes	Yes, except Load position in Automatic mode*	No	Yes, except Load position in Automatic mode
Rinseback (Return RBCs)	Yes	Yes	Yes	Yes	No	Yes
Rinseback (Recirculating)	No	No	No	No	No	No
Rinseback (Evacuating, Rinse Channel)	Yes	No	Yes	No	No	No
Unload Set	Yes	Yes	Yes	Yes	No	Yes

* For ELP, Platelet, and WBC procedures, the plasma valve can be moved only during Manual operation. When you switch from Manual operation to Automatic operation, the plasma valve moves back to the Return position unless plasma is being collected.

** In single-needle runs, the collect and plasma valves will not move until the end of the return cycle.

CHANGE MODE KEY

The CHANGE MODE key is used to display the mode change selection message, allowing you to change the operating mode during a procedure. When a selection is made, the message is removed and the Spectra system goes to the designated mode (and state). If no selection is made, the message will be removed in 30 seconds without changing the current mode (and state). Also, pressing the CLEAR, CHANGE MODE, VALVE, or MENU ON/OFF key removes the message.

The CHANGE MODE key selection message is described below.

MODE CHANGE SELECTION MESSAGE

```
1 = Load Set, 2 = Prime, 3 = Run, 4 = Rinseback,
5 = Unload Set, 6 = Diagnostics.
```

- Press 1 = advances to Load Set mode (Loading state)
- Press 2 = advances to Prime mode (Priming AC state)
- Press 3 = advances to Run mode (ReRun state)
- Press 4 = advances to Rinseback mode (Pre-Rinseback state)
- Press 5 = advances to Unload Set mode (Unloading state)
- Press 6 = advances to Diagnostics mode (includes alarm tests)
- Press CLEAR = removes selection message from screen

See SECTION 9 - DIAGNOSTICS for information on Spectra diagnostics.

VALID MODE CHANGES

Some mode changes will not be allowed at certain times due to donor/patient safety concerns. When an invalid mode change is selected, the following message will display for 4 seconds: "INVALID MODE CHANGE! Select another mode or CLEAR." See Table A-2 for valid mode changes.

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Table A-2. Valid Mode Changes

Mode (State)	Load Set	Prime	Run	Rinse-back	Unload Set	Diagnos-tics
Preload	Yes	No	No	No	Yes	Yes
Loading Select Set, Single Needle, Set Return Flow Scale	Yes	No	No	No	Yes	Yes
Load Set (Preload Loading, Set Select)	Yes	No	No	No	Yes	Yes
Load Set (Close Clamps, Connect Fluids)	Yes	Yes	No	Yes	Yes	Yes
Prime (RePrime to Test Bubble)	Yes	Yes	No	Yes	Yes	Yes
Prime (PrimeConnects to Patient Data)	Yes	Yes	Yes	Yes	Yes	Yes
PreRun to Run	No	No	Yes	Yes	No	No
Rinseback (Clamp Access, Collecting)	No	No	Yes	Yes	Yes	No
Rinseback (Return RBCs to Rinse Channel)	No	No	No	Yes	Yes	No
Unload Set (Disconnect, Final Values)	Yes	Yes	No	Yes	Yes	Yes
Unload Set (Unloading)	Yes	No	No	No	Yes	Yes

MENU ON/OFF KEY

The MENU ON/OFF key is used to display selection messages, allowing you to choose a number of options. When a selection is made, the current message is either removed (if an action is selected) or replaced by another message. The message will display for 30 seconds unless the MENU ON/OFF key is pressed again or the CLEAR key is pressed from the first option selection message. Pressing the CHANGE MODE or VALVE key will also remove the message.

When the MENU ON/OFF key is pressed, the MENU LED turns on. The LED stays on as long as you are making selections from the messages associated with the MENU ON/OFF key. This includes the *data entry messages* (donor/patient data) if they are chosen through the MENU ON/OFF key instead of waiting until the messages are displayed after Prime mode is complete. As long as the MENU LED is on, you may remove the *option selection messages* by pressing the MENU ON/OFF key for a second time (which also turns off the MENU LED).

The MENU ON/OFF key selection messages are described in the following pages.

FIRST OPTION SELECTION MESSAGE

1 = Data Entry, 2 = Pressure Display, 3 = CCM, 4 = Air Remove, 5 = Strobe, 6 = Configuration

- Press 1 = displays *donor/patient data entry messages*
- Press 2 = displays *pressure selection message*
- Press 3 = displays *Collect Concentration Monitor display*
- Press 4 = displays *air remove selection message*
- Press 5 = displays *strobe on/off selection message*
- Press 6 = displays *first configuration selection message*

1 = Data Entry, 2 = Pressure Display, 3 = CCM, 4 = Air Remove, 5 = Strobe, 6 = Config., 7 = SN.

This version of the *first option selection message* is displayed only if the single-needle mode is in effect or if the Single-Needle Option is installed and activated and the run may be converted from dual needle to single needle.

- Press 7 = displays applicable *single-needle message*

Option 1 = Donor/Patient Data Entry Messages (Displayed First Time)

Donor/patient data entry messages are displayed at the end of the Prime mode unless you choose to enter the data before or during the Prime mode. This can be done by selecting "Data Entry" from the first option selection message. The first time into "Data Entry" during a procedure, you will see the same series of sequential selection messages. If you cancel out of the selection message screens by pressing the MENU

ON/OFF key again (before responding to all the messages), all the selection messages will have to be responded to at the end of the Prime mode.

Once responses have been made to all the sequential messages, the donor/patient data selections are set for the procedure. After that, selecting "Data Entry" will not force you to go through the sequential messages. Instead, the *donor/patient data entry messages* will be displayed to allow you to modify only the desired parameters. (See Appendix B for a summary of the allowable ranges for numbers entered in donor/patient data.)

Following is a description of the sequential *donor/patient data entry messages*. The description of the usage of the ENTER and CLEAR keys only applies to the first use of the messages during a procedure. When a message is responded to, either with a selection or by pressing the ENTER key, the next message in the series is displayed. The CLEAR key usually causes the preceding message to be displayed again. This allows you to back up through the messages, making further changes as needed. When backing up through the messages, the displayed defaults will reflect the previously selected values. Thus, you may back up to a message, modify that value, and then press ENTER repeatedly to return to the next message that requires a response.

If donor/patient data entry is attempted before selecting the type of blood tubing set that will be used for the procedure, the following message will be displayed: "MUST SELECT SET TYPE BEFORE ENTERING DATA!"

NOTE

If the run results are desired prior to setting up for a procedure, select the tubing set type, use the *donor/patient data entry messages*, and review the results.

- **Sex Entry Message**

(First time, or if Male was previously chosen.)

Select sex: 1 = Male, 2 = Female. (ENTER = Male)

(Second time, if Female was previously chosen.)

Select sex: 1 = Male, 2 = Female. (ENTER = Female)

(ENTER LED is flashing.)

- Press 1 = donor/patient is male
- Press 2 = donor/patient is female
- Press ENTER = leave selection unchanged – use default data in parenthesis
- Press 1, 2, or ENTER = *height entry message* is displayed
- Press CLEAR = redisplays *first option selection message*

- **Height Entry Message**

(Metric units chosen in configuration selection.)

Enter height, in centimeters: { 0 }

NOTE

The Spectra system can be configured for metric units by accessing the MENU ON/OFF key, Selection 6, Configuration. See discussion of *configuration selection messages* later in this Appendix.

Enter a height within the allowable limits. No default is allowed the first time. After the number is entered and ENTER is pressed, the *weight entry message* is displayed. Pressing CLEAR displays the sex entry message.

(English units chosen in configuration selection. Enter feet.)

```
Enter height,
in feet:  { 0 }, and/or inches:  0
```

Enter feet when the feet number is highlighted by "{ }". Pressing ENTER moves the highlight to the inches number as shown below. Pressing CLEAR displays the *sex entry message*.

(English units chosen in configuration selection. Enter inches.)

```
Enter height,
in feet: ____, and/or inches:  { 0 }
```

Enter a height within the allowable limits. No default is allowed the first time. The total height in inches is the sum of the feet number times twelve, plus the inches number. You may decide to enter the height in inches only by leaving the feet number at zero. After the inches number is entered, the total height is calculated. If it is not within the allowable limits, the message remains, the feet number is highlighted again, and a short alarm is sounded.

The first time the message is displayed, the values shown are zero, indicating no default. If the message is displayed again, the previously entered height will be shown in the feet and inches format (for example, 70 inches will be shown as 5 feet, 10 inches). You can select this default by pressing ENTER twice.

After the inches number is entered and ENTER is pressed, the *weight entry message* is displayed (if the total height is valid). Pressing CLEAR while entering inches will move the highlight to the feet number.

- **Weight Entry Message**

(Metric units chosen in configuration selection.)

```
Enter weight,
in kilograms:  { 0 }
```

(English units chosen in configuration selection.)

```
Enter weight,
in pounds:  { 0 }
```

You must enter a weight within the allowable limits. No default is allowed the first time. After the number is entered and ENTER is pressed, the *total blood volume (TBV) message* is displayed. Pressing CLEAR displays the *height entry message*.

- **TBV Message**

This message displays the calculated total blood volume and the values that were used in the calculation.

```
Total blood volume = _______ ml.
(____ in, _____ lbs, Female). OK (YES/NO)?
```

- Press ENTER/YES = displays *hematocrit entry message*
- Press CLEAR/NO = redisplays *weight entry message*

References

1. Nadler S.B., *et al.*, "Prediction of Blood Volume in Normal Human Adults," *Surgery* 1962;51:224.
2. Allen T.H., , *et al.* "Prediction of Blood Volume and Adiposity in Man From Body Weight and Cube of Height," *Metabolism* 1959;39:307.

- **Hematocrit Entry Message**

```
Enter hematocrit (%): { 41 }
```

- Enter hematocrit as a whole number between 10% and 70% (Decimal point not required.)
- The first-time default will be 45% for males and 41% for females
- Press ENTER = displays *first procedure-dependent message*
- Press CLEAR = redisplays *TBV message*

Procedure-Dependent Messages

After responses are made to all the *donor/patient data entry messages*, the mandatory donor/patient data selections are complete. The algorithms calculate default values for all end-of-run values. Therefore, you now have the option of exiting "Data Entry" and changing the end-of-run values at a later time by selection "Data Entry."

The messages displayed are different, depending on which procedure is being run. They are described here in a different section for each type of procedure.

- **Platelet Pre-count Entry Message**

```
Enter platelet pre-count,
in cells/microliter: { 250 } x 1000
```

- Press ENTER = displays *procedure-dependent messages* or *platelet procedure selection message*
- Press CLEAR = redisplays *hematocrit entry message*

This message is displayed only for ELP and Platelet sets, not for WBC, TPE, or RBCX sets. For collect procedures, the first-time default will be 250 [250,000 platelets per microliter]. If the value entered is

greater than 400 [400,000 platelets per microliter], the *platelet procedure selection message* will be displayed.

- **Platelet Procedure Selection Message**

(First time, or if Collect was previously chosen.)

```
Select procedure:  1 = Donor Collect,
2 = Patient Deplete.  (ENTER = Collect)
```

(Second time, or if Deplete was previously chosen.)

```
Select procedure:  1 = Donor Collect,
2 = Patient Deplete.  (ENTER = Deplete)
```

(ENTER LED is flashing.)

- Press 1 = select collect platelets from donor
- Press 2 = select deplete platelets from patient
- Press ENTER = leave selection unchanged (use default)
- Collect Selected = displays *concurrent plasma selection message*
- Deplete Selected = displays *platelet depletion results message*
- Press CLEAR = redisplays *platelet pre-count entry message*

- **Concurrent Plasma Selection Message**

```
1 = no plasma, 2 = collect plasma
    (ENTER = no plasma)
```

- Press 1 or ENTER = tells system not to concurrently collect plasma with platelets. *Platelet yield message* is displayed.
- Press 2 = tells system to concurrently collect plasma with platelets. *Platelet yield message* is displayed.
- Press CLEAR = redisplays *platelet pre-count entry message*

Platelet Collect Procedure

- **Platelet Yield Message**

In this message, the algorithms calculate and display the predicted yield and concentration, based on all available information. The initial default is time = 100 minutes and target collect concentration = 1,400,000 platelets per microliter.

```
Yield = __.__E11, collect = _____, conc = __,___,
plasma = _____, time = ___ min.  OK (YES/NO)?
```

- Press ENTER/YES = exit "Data Entry"
- Press CLEAR/NO = displays *platelet settings message*

- **Platelet Settings Message**

Change: 1 = run time, 2 = inlet flow, 3 = collect volume, 4 = conc., 5 = plasma.

(ENTER LED is off.)

- Press 1 = braces around run time
- Press 2 = braces around inlet flow
- Press 3 = braces around collect volume
- Press 4 = braces around collect concentration
- Press 5 = braces around plasma volume
- Press 9 = redisplays *concurrent plasma selection message*
- Press CLEAR = redisplays *platelet yield message*

Using arrow keys, change selected value. The up arrow key increases the value; the down arrow key decreases it. Affected values will also be changed. When satisfied that changed and affected values are appropriate, press ENTER to return to *platelet yield message*. CLEAR returns to change *platelet settings message*.

Platelet Deplete Procedure

- **Platelet Depletion Results Message**

Inlet volume = _____ml, inlet flow = ___.__ time = ___min. collect______. OK (YES/NO)?

- Press ENTER/YES = exit "Data Entry"
- Press CLEAR/NO = displays *platelet depletion settings message*

The initial default for process time is 120 minutes.

- **Platelet Depletion Settings Message**

Change: 1 = run time, 2 = inlet flow, 3 = collect volume, 4 = pre-count.

(ENTER LED is off.)

- Press 1 = braces around run time
- Press 2 = braces around inlet flow
- Press 3 = braces around collect volume
- Press 4 = braces around pre-count

Press CLEAR = redisplays *platelet depletion results message*

Using arrow keys, change selected value. The up arrow increases its value; the down arrow decreases it. Affected values will also be changed. When satisfied that change and affected values are appropriate, press ENTER to return to the *platelet depletion results message*. Pressing CLEAR will redisplay the *platelet depletion settings message*.

White Blood Cell Removal Procedure

- **WBC Procedure Selection Message**

```
Select procedure:  1 = MNC, 2 = PMN.
    (ENTER = MNC)
```

- Press 1 = selects mononuclear cell (MNC) removal. *WBC results message* displays.
- Press 2 = selects polymophnuclear (PMN) cell or granulocyte removal. *WBC results message* displays.
- Press ENTER = selected default, which is initially MNC.
- Press CLEAR = redisplays *hematocrit entry message*.

- **WBC Removal Results Message**

```
Inlet volume = _____ml, inlet flow = ___.__,
time = ___min. collect = _.___  OK (YES/NO)?
```

- Press ENTER/YES = exit "Data Entry"
- Press CLEAR/NO = displays *WBC removal settings message*

The initial default for time is 120 minutes.

- **WBC Removal Settings Message**

```
Change:  1 = run time, 2 = inlet flow,
3 = collect volume, 4 = inlet volume.
```

(ENTER LED is off.)

- Press 1 = braces around run time
- Press 2 = braces around inlet flow
- Press 3 = braces around collect volume
- Press 4 = braces around inlet volume
- Press 9 = redisplays *WBC procedure selection message*
- Press CLEAR = redisplays *WBC removal results message*

Using arrow keys, change selected value. The up arrow increases the value; the down arrow decreases it. Affected values will also be changed. When satisfied that changed and affected values are appropriate, press ENTER to return to the *WBC removal results message*. Pressing CLEAR will redisplay the *WBC removal settings message*.

- **Replacement Fluid Entry Message**

Replacement fluid: 1 = Albumin/Saline, 2 = Plasma. (ENTER = Albumin/Saline)

(ENTER LED is flashing.)

- Press 1 = albumin/saline
- Press 2 = plasma
- Press ENTER = displays *TPE fluid balance entry message* (fluid selection unchanged)
- Press CLEAR = redisplays *hematocrit entry message*

NOTE

If the replacement fluid is changed during the Run mode, this message can be selected again and the replacement fluid changed, thereby, automatically adjusting the flow rates and procedure end points.

- **TPE Fluid Balance Entry Message**

This value sets the replaced/remove flow rate ratio [75% to 150%] based on the following equation:

$$Q_{replace} = (\text{balance}/100) \times (Q_{plasma} - Q_{AC})$$

Enter fluid balance desired: { 100 }%

- Either press ENTER to accept the default value of 100%, or use the arrow keys to change to a value between 75% and 150% and then press ENTER. The *plasma exchange results message* displays.
- Press CLEAR = redisplays the *replacement fluid entry message*

- **Plasma Exchange Results Message**

This message shows the total replacement fluid to be used, the volume to be removed, the AC volume to be used, and the total run time. The value in parenthesis is the number of patient plasma volumes that these values represent. The first time this message is displayed, the value used to generate the figures is retrieved from the configuration data. This value is normally 1.0, but you may change the system's default using the *configuration selection message*. These are true patient plasma volumes. The removed bag volume shown will be larger than the multiple of plasma volumes would suggest because it will also contain a certain amount of anticoagulant.

Therefore, the calculations for the first time the *exchange results message* is displayed proceed as follows:

- The inlet:AC ratio and patient hematocrit will determine the percentage of ACD-A to be expected in the plasma bag.
- The plasma removed bag target volume is set to contain the number of patient plasma volumes specified from configuration data, plus the ACD-A percentage expected.
- The run time is calculated to be the plasma removed bag volume divided by the plasma pump flow rate.
- The ACD-A volume to be used is the run time multiplied by the AC pump flow rate.
- The replacement fluid volume is the run time multiplied by the replace pump flow rate.

Replace = _____ml, removed = _____ml (_._), AC = ___ml, time = ___min. OK (YES/NO)?

- Press ENTER/YES = exit "Data Entry"
- Press CLEAR/NO = redisplays *change TPE values message*

- **Change TPE Values Message**

Change: 1 = Replace volume, 2 = Removed volume, 3 = Run time, 4 = Inlet flow.

(ENTER LED is off.)

- Press 1 = braces around replace volume
- Press 2 = braces around removed volume
- Press 3 = braces around run time
- Press 4 = braces around inlet flow
- Press 9 = redisplays *TPE fluid balance entry message*
- Press CLEAR = redisplays *exchange results message*

Using arrow keys, change selected value. The up arrow increases the value; the down arrow decreases it. Affected values will also be changed. When satisfied that changed and affected results are appropriate, press ENTER to return to the *plasma exchange results message*. Pressing CLEAR will return to the *change TPE values message*.

Red Blood Cell Exchange Procedure

- **RBCX Replacement Fluid Hematocrit Entry Message**

Enter average replacement fluid hematocrit (%):{80}

- Either press ENTER to accept the default value of 80%, or use the arrow keys to change to a value between 0% and 99% and then press ENTER. (0% would be a red cell deplete.) The *RBCX end hematocrit entry message* will display.

  To calculate the correct hematocrit, determine the average (by volume) of the hematocrits of all replacement red cell bags.

- Press CLEAR = redisplays the *hematocrit entry message*

- **RBCX End Hematocrit Entry Message**

Enter end hematocrit (%): { 0 }

- Use the arrow keys to change 0% to a value between 9% and 70% for the patient hematocrit desired at the end of the procedure. Then press ENTER. The *RBCX hematocrit check message* will display.

  Enter the value of the desired patient hematocrit at the end of the procedure. If the average hematocrit of the replacement fluid bags is zero (signifying a red blood cell deplete), the end hematocrit must be less than or equal to the initial hematocrit (the value entered in the *hematocrit entry message*).

- Press CLEAR = redisplays the *RBCX replacement fluid hematocrit entrymessage*

- **RBCX Hematocrit Check Message**

Patient Hct = ___%, End Hct = ___%, Average replace Hct = ___%. OK(YES/NO)?

- Press ENTER/YES = displays the *RBCX fluid balance entry message*
- Press CLEAR/NO = redisplays *hematocrit entry screen*

This message allows you to confirm that all of the hematocrits have been entered correctly.

- **RBCX Fluid Balance Entry Message**

Enter fluid balance desired: FB = {100}%.

- Either press ENTER to accept the default value of 100%, or use the arrow keys to change to a value between 75% and 150% and then press ENTER. The calculated *RBCX replacement fluid YES/NO message* displays.

- Press CLEAR = redisplays the *RBCX hematocrit check message*

This value sets the replaced/removed flow rate ratio based on the following equation:

$$Q_{repl} = [\text{Balance}/100) \times Q_{rbc}] - Q_{AC}$$

- **Calculate RBCX Replacement Fluid YES/NO Message**

Calculate replacement fluid volume needed YES/NO)?

- Press ENTER/YES = displays *desired fraction of red cells remaining message*
- Press CLEAR/NO = displays *RBCX replacement volume data entry message*

"NO" would be the appropriate response if the RBCX data are being entered when you are ready to actually begin the RBCX procedure and, thus, know the *actual* volume of the replacement cell fluid.

RBCX Patient Data Entry for Calculation of Replacement Volume Needed

It is frequently desirable to order the red blood cell replacement fluid a day or two before a red blood cell exchange procedure is to be performed. To determine the correct volume of red blood cell replacement fluid to order:

- Select 4 (RBCX) from the *set selection message*
- Press MENU ON/OFF key
- Select 1 (Data Entry) from the *first option selection message*

The following messages will be displayed. Note that they *also* will be displayed in the unlikely event that ENTER/YES is pressed in response to the *calculate RBCX replacement fluid YES/NO message* above.

- **Desired Fraction of Red Blood Cells Remaining Message**

Enter desired Fraction of Red Cells Remaining: FCR = {0} %

NOTE

This screen will be skipped if zero was entered as the average hematocrit of the red blood cell replacement fluid, indicating a red cell depletion procedure.

- Use the arrow keys to change 0% to a value between 1% and 100%, which represents the percentage of original defective hemoglobin that should remain at the end of the RBCX procedure. Then press ENTER.

- The Spectra system will use the value you enter to calculate the volume of replacement red blood cells needed. If this volume is valid, the *RBCX replacement volume calculation results message* will appear. If the result is not valid, the "Invalid Replacement Fluid Volume" warning alarm will be displayed. See this message in SECTION 11 – TROUBLESHOOTING.

- Press CLEAR = redisplays the *calculated RBCX replacement fluid YES/NO message*

- **Replacement Volume Calculation Results Message**

Replace = ___ ml, FB = ___ %, FCR = ___ %, End Hct = ___ %, time = ___ min. OK (YES/NO)?

This message provides the following values:

- Calculated red blood cell replacement volume
- Fluid balance (ratio of replaced/removed red blood cell flow rates) using either the default value of 100% or the value entered in response to the *RBCX fluid balance entry message*
- Fraction of red blood cells remaining entered in response to the desired fraction of red blood cells remaining message above
- End hematocrit entered earlier
- Calculated process time

To respond to *replacement volume calculation results message*:

- Press ENTER/YES if the calculated red blood cell replacement volume is adequate. The *RBCX replacement volume data entry message* is displayed.
- Press CLEAR/NO if the calculated red blood cell replacement volume is too large or if time is too long. The *change RBCX replacement volume settings message* is displayed.

- **Change RBCX Replacement Volume Settings Message**

Change: 1 = Fluid Balance, 2 = FCR, 3 = End Hct.

- Press 1 = braces around fluid balance
- Press 2 = braces around fraction cells remaining
- Press 3 = braces around end hematocrit
- Press CLEAR = redisplays *replacement volume calculation results message*

Replace = ___ ml, FB = ___ %, FCR = ___ %, End Hct = ___ %, time = ___ min.

Using the arrow keys, change the selected value. The up arrow increases the value; the down arrow decreases it. Affected values will also be changed. When satisfied that changed and affected results are appropriate, press ENTER to redisplay the *replacement volume calculation results message*. Pressing CLEAR will redisplay the *change RBCX replacement volume settings message*.

When you change the values for the fluid balance, desired fraction of red cells remaining, or end hematocrit percentage, the replacement cell volume or replacement cell volume and time are recalculated. If the calculation value(s) is not valid, the "Limits Exceeded" warning beep will sound and the changed value will be returned to its original value.

Normal RBCX Patient Data Entry

The messages below are accessed by selecting CLEAR/NO in response to the *calculated RBCX replacement fluid YES/NO message* or ENTER/YES in response to the *replacement volume calculation results message*.

- **RBCX Replacement Volume Data Entry Message**

Enter total replacement fluid volume: { 0 } ml.

- Use the arrow keys or keypad to change 0 ml to a value between 100 and 9999 ml and then press ENTER.

- The Spectra system will use the value you enter to calculate the process time required and the percentage of defective hemoglobin remaining at the end of the RBCX procedure. If these two values are valid (time greater than 0 minutes and less than 300 minutes), the *RBCX results message* will be displayed. If the results are not valid, the "Invalid Process Time" warning alarm will be generated. See this message in SECTION 11 - TROUBLESHOOTING.

- Press CLEAR = redisplays calculated RBCX replacement fluid YES/NO message.

- **RBCX Results Message**

Replace = ___ ml, FB = ___ %, FCR = ___ %, End Hct = ___ %, time = ___ min. OK (YES/NO)?

This message provides the following values:

- Red blood cell replacement volume entered in response to the *RBCX replacement volume data entry message*

- Fluid balance (ratio of replaced/removed red blood cell flow rates) entered in response to the *RBCX fluid balance entry message*

- Calculated fraction of red blood cells remaining

- End hematocrit entered in response to the *RBCX end hematocrit entry message*

- Calculated process time

To respond to *RBCX results message*:

- Press ENTER/YES if the calculated fraction of red cells remaining and process time values are adequate. You will exit "Data Entry."

- Press CLEAR/NO if the fraction of red blood cells remaining is too large. The *change RBCX settings message* is displayed.

- **Change RBCX Settings Message**

Change: 1 = Fluid Balance, 2 = replacement cell volume, 3 = End Hct.

- Press 1 = braces around fluid balance
- Press 2 = braces around replacement cell volume
- Press 3 = braces around end hematocrit
- Press CLEAR = redisplays *RBCX results message*

Replace = ___ ml, FB = ___%, FCR = ___%, End Hct = ___%, time = ___ min.

Using the arrow keys or keypad, change the selected value. The up arrow increases the value; the down arrow decreases it. When satisfied that changed and affected results are appropriate, press ENTER to redisplay the *RBCX results message*. Pressing CLEAR redisplays the *change RBCX settings message*.

When you change the values for the fluid balance replacement cell volume or end hematocrit, the process time is recalculated. If the calculated valueis not valid, the "Limits Exceeded" warning beep will sound and the changed value will be returned to its original value. Changing the replacement volume or end hematocrit after the beginning of the Run mode invalidates the displayed end of run fraction of cells remaining (FCR) as well as the FCR that was predicted at the beginning of the procedure.

Option 1 = Donor/Patient Data Entry Messages (Displayed Subsequently)

- **Donor/Patient Data Selection Message**

1 = Change procedure, 2 = Change donor information, 3 = Run results, 4 = AC data

(ENTER LED is off.)

- Press 1 = displays appropriate *procedure selection message*. For example, if you are currently in an ELP or Platelet procedure, the *platelet procedure selection message* will be displayed, and, if you are in a WBC procedure, the *WBC procedure selection message* will be displayed.
- Press 2 = displays *donor/patient data entry selection message*
- Press 3 = redisplays *procedure-dependent messages*
- Press 4 = displays *AC status message*
- Press CLEAR = redisplays the *first option selection message*

If you select "1 = Change procedure" when running a single-needle procedure or using a TPE or RBCX tubing set, the following message is displayed on the screen for 3 seconds: "No procedure to select with SN, TPE, or RBCX set."

If you select "3 = Run results," one of the following messages is displayed, depending on the procedure selected:

Platelet Collection = *Platelet Yield Message*
Platelet Depletion = *Platelet Depletion Results Message*
Therapeutic Plasma Exchange = *Plasma Exchange Selection Message**
Red Blood Cell Exchange = *RBCX Message**
White Cell Removal = *WBC Removal Settings Message*

*The two messages marked with an asterisk are described below. The remainder of the messages are described above under **Procedure-Dependent Messages**.

- **Donor/Patient Data Entry Selection Message**

Change: 1 = Sex, 2 = Height, 3 = Weight, 4 = HCT, 5 = Platelet.

(ENTER LED is off.)

- Press 1 = displays *sex entry message*
- Press 2 = displays *height entry message*
- Press 3 = displays *weight entry message*
- Press 4 = displays *hematocrit entry message*
- Press 5 = displays *platelet pre-count entry message*
- Press CLEAR = redisplays *donor/patient data selection message*

- **Plasma Exchange Selection Message**

Change: 1 = Replacement fluid, 2 = Fluid balance, 3 = End results.

(ENTER LED is off.)

- Press 1 = displays *replacement fluid entry message*
- Press 2 = displays *fluid balance entry message*
- Press 3 = displays *exchange results message*
- Press CLEAR = redisplays *donor/patient data selection message*

- **RBCX Message**

Change: 1 = Average replacement fluid hematocrit, 2 = End results.

- Press 1 = displays *RBCX replacement fluid hematocrit entry message*
- Press 2 = displays *RBCX results message*
- Press CLEAR = redisplays *donor/patient data selection message*

- **AC Status Message**

AC infusion rate: __.__ ml/min/liter TBV. ml AC in bags: collect:___, plasma:___

In addition to displaying the *current* AC infusion rate, this message also displays the *predicted* number of milliliters of anticoagulant in both the collect bag or bags and the plasma bag at the end of the run. The values displayed in this message are not valid during RBCX procedures.

- Press CLEAR = redisplays *donor/patient data selection message*

Option 2 = Pressure Sensor Display Messages (Chosen From *First Option Selection Message*)

- **Pressure Selection Message**

1 = Current pressures, 2 = Set alarm limits.

- Press 1 = displays *pressure sensor display*
- Press 2 = displays *pressure limit entry message*
- Press CLEAR = redisplays first option selection message

- **Pressure Sensor Display**

AC	Inlet	Plasma	Collect Replace	Inlet AC Ratio	Spin RPM
__.__	___.__	___.__	___.__	___.__	_____
Access: -_____, Return: -_____ (mmHg)					

The *pressure sensor display* can be used to monitor the donor/patient access and return pressures. (For single-needle procedures, the *pressure sensor display* can only be used to monitor donor/patient access pressure.) The pressures are displayed on the lower line and the pump flow rates are displayed on the top line. This allows you to adjust pump flow rates and observe the changes in access and return pressures.

The pressure sensor display remains on the screen until one of the following keys is pressed: CLEAR, VALVE, CHANGE MODE, or MENU ON/OFF. The MENU LED remains on. Pressing the CLEAR key redisplays the *first option selection message.*

- **Pressure Limit Entry Message**

If you are in the Prime mode when you select "2 = Set alarm limits" from the *pressure selection message*, the following message will be displayed for four seconds:

Must be in Run before alarm limits can be changed!

Reselect "2 = Set alarm limits" after the Run mode has begun.

If you are in the Run mode when you select "2 = Set alarm limits," the following message is displayed:

```
Access pressure low limit:   -{250}
Return pressure high limit:  400
```

NOTE

During single-needle procedures, the *return pressure high limit* cannot be adjusted.

- Either press ENTER key to accept default access pressure low limit of 250 mmHg, or use arrow keys to change *access pressure low limit* to a value between -50 and -250 mmHg and press ENTER key. Use the up arrow key to enter a less negative number, for example, to change from -250 to -200. The *return pressure high limit* entry is then highlighted so you can revise it as well.
- Press ENTER key to accept the default *return pressure high limit* of 400 mmHg, or use the arrow keys to change the *return pressure high limit* to a value between 50 and 400 mmHg and press the ENTER key. The *pressure selection message* is redisplayed.

Option 3 = Collect Concentration Monitor Display (Chosen From *First Option Selection Message*)

```
CCM: Current Yield = __.__E11    1 = On*, 2 = Off
End Run Yield = __.__E11, conc. = _______
```

The asterisk indicates whether the CCM is On or Off.

The CCM uses two light sources to transmit light through a molded cuvette on the platelet collect line. The light intensity at the angular and central light receiving points is processed by the Spectra system to display yields and concentration.

- The current yield is the platelet yield collected at any point in the procedure.
- The end run yield is the combination of the current yield and the remaining portion of the predicted yield displayed to the eleventh power (for example, 4E11 = 4×10^{11}. This is the CCM predicted observation of the yield at the end of the procedure.
- Concentration is the platelet concentration in the collect bag at the end of the run.
- The on/off function allows you to turn off the CCM function for current procedure only.
  - Press 1 = turns CCM on to enable CCM warnings
  - Press 2 = turns CCM off to stop CCM warnings
  - Press CLEAR = redisplays *first option selection message*

The MENU LED remains on.

If the saline calibration sequence failed (which means the CCM LEDs are not on) or if the CCM is not in the Run mode, the following screen will appear in place of the *CCM display*:

CCM not operational – this run only.

To remove this message, press CLEAR or MENU ON/OFF key. For additional information about this message, see SECTION 11 – TROUBLESHOOTING.

Option 4 = Air Remove Selection Message (Chosen From *First Option Selection Message*)

Press and hold following key to remove air from: 1 = Inlet chamber, 2 = Return.

(ENTER LED is off.)

Pressing and holding the 1 key removes air from the inlet air chamber. If the 2 key is pressed and held, air is removed from the return air chamber. The pump flow rates are kept at their current values. However, if the inlet pump is below a threshold flow rate, it is set to the threshold value.

Holding the key down for more than 30 seconds stops the air remove function. The key must be pressed again to restart the air removal. When the key is released, the pumps revert to their original flow rates and all valves are returned to their original positions.

Observe the waste divert line for air during an air removal operation. When air is above the waste valve, the operation can be stopped. Care must be taken to prevent blood from being diverted into the waste bag during this operation.

The *air remove selection message* remains on the screen until one of the following keys is pressed: CLEAR, VALVE, CHANGE MODE, or MENU ON/OFF. The MENU LED remains on. Pressing the CLEAR key redisplays the *first option selection message*.

If the return valve position detector indicates that the valve is malfunctioning, the air remove function will not be allowed and the following message will be displayed:

RETURN VALVE BAD – CANNOT DO AIR REMOVE!

To remove this message, press CLEAR or the MENU ON/OFF key.

Option 5 = Strobe On/Off Selection Message (Chosen From *First Option Selection Message*)

1 = Strobe off, 2 = Strobe on.

(ENTER LED is off.)

- Press 1 = turn off centrifuge strobe
- Press 2 = turn on centrifuge strobe
- Press CLEAR = redisplays *first option selection message*

Blood separation can only be observed with the strobe turned on.

Option 6 = First Configuration Selection Message (Chosen From *First Option Selection Message*)

The following parameters are selectable and will remain in effect until altered. Changes to the parameters always affect the current procedure immediately. See the **SETTING CONFIGURATION VALUES** section of SECTION 1 - INTRODUCTION for more information on these configurable parameters and their purposes.

Configuration: 1 = Height/weight units, 2 = Decimal Point, 3 = AC rate, ENTER = more.

(ENTER LED is flashing.)

- Press 1 = displays *height/weight unit selection message*
- Press 2 = displays *decimal point/thousands separator selection message*
- Press 3 = displays *default AC infusion rate entry message*
- Press ENTER = displays *second configuration selection message*
- Press CLEAR = redisplays *first option selection message*

- **Height/Weight Unit Selection Message**

Select height/weight units: 1 = English (in, lbs), 2 = Metric (cm, kg).

(ENTER LED is off.)

- Press 1 = enter height in inches, weight in pounds
- Press 2 = enter height in centimeters, weight in kilograms
- Press CLEAR = redisplays *first configuration selection message*

- **Decimal Point/Thousands Separator Selection Message**

Select character for decimal point: 1 = Period (.), 2 = Comma (,).

(ENTER LED is off.)

- Press 1 = period is decimal point, comma is thousands separator
- Press 2 = comma is decimal point, period is thousands separator
- Press CLEAR = redisplays *first configuration selection message*

- **Default AC Infusion Rate Entry Message** (Used for ELP and Platelet collection procedures only)

Before the *default AC infusion rate entry message* is displayed, the following message will be displayed: "CAUTION: Higher AC infusion rate may increase donor reaction."

Enter default AC infusion rate, in ml/min per liter blood volume: {0.80}

Enter the coefficient that the algorithms will use to calculate the starting AC flow rate. (The coefficient is multiplied by the donor's total blood volume in liters.) The number ranges from 0.80 to 1.10 ml of AC/min/liter of TBV for direct entry.

If the default AC infusion rate is changed during a run, a one-time "AC infusion rate was changed last run" warning will be generated at the start of the next run. See SECTION 11 – TROUBLESHOOTING.

- **Second Configuration Selection Message**

Configuration: 1 = plasma collect, 2 = plasma volumes, 3 = ratio, ENTER = more.

(ENTER LED is flashing.)

- Press 1 = displays *total plasma collect selection message*
- Press 2 = displays *plasma volumes entry message*
- Press 3 = displays *ratio configuration selection message*
- Press ENTER = displays *third configuration selection message*
- Press CLEAR = redisplays *first configuration selection message*

- **Total Plasma Collect Selection Message**

Total plasma collect limited by: *1 = volume or 2 = percent of TBV

(ENTER LED is off.)

The asterisk ("*") indicates which option is currently selected. Volume is the default selection.

- Press 1 = displays *maximum plasma collect volume entry message*
- Press 2 = displays *total plasma collect percent entry message*
- Press CLEAR = redisplays *second configuration selection message*

- **Total Plasma Collect Volume Entry Messages** (Used during ELP and Platelet collection procedures only)

  - **Maximum Plasma Collect Volume Entry Message**

Enter total plasma collect: {600} ml, or 500 ml if weight under 175 lbs.

Press ENTER to accept 600 ml as the default value for the total volume of plasma (plasma and all collect bags combined) that can be collected from a donor during a platelet collection procedure before a warning is generated. The *second plasma collect volume entry message* will then display.

If the default value of 600 ml is not acceptable, enter another value between 10 and 1500 ml and press ENTER. The *second plasma collect volume entry message* will then display.

  - **Second Plasma Collect Volume Entry Message**

Enter total plasma collect: 600 ml, or {500} ml if weight under 175 lbs.

Press ENTER to accept 500 ml as the default value for the total volume of plasma that can be collected from donor weighting less than 175 pounds (or 80 kg) before a warning is generated. The *donor weight cutoff entry message* will then display. 500 ml can also be accepted at this point if you plan to change the "weight under" value in the next data entry screen to some other value but want the maximum number of milliters of plasma collected from a donor under that new weight to remain at 500 ml.

If the default value of 500 ml is not acceptable, enter another value between 10 and 1500 ml and press ENTER. The *donor weight cutoff entry message* will then display.

- **Donor Weight Cutoff Entry Message**

Enter total plasma collect: 600ml or 500 ml if weight under {175} lbs.

Press ENTER to accept 175 pounds (or 80 kg) as the default value for donor weight that will trigger the "second plasma collect volume" value entered in the *second plasma collect volume entry message* above. 175 pounds (or 80 kg) could also be accepted at this point even if you have already changed the "second plasma collect volume" value in the *second plasma collect volume entry message* above to a value other than the default of 500 ml.

If the default value of 175 pounds (or 80 kg) is not acceptable, enter another value between 0 and 500 pounds (or 0 to 230 kg) and press ENTER.

Press CLEAR once to return to the *total plasma collect selection message.*

Press CLEAR twice to return to the *second configuration selection message.*

- **Total Plasma Collect Percent Entry Message** (Used during ELP and Platelet collection procedures only)

Enter total plasma collect: {12} percent of TBV

Press ENTER to accept 12% as the default value for the percent of total blood volume of plasma (plasma and cell collect bags combined) that can be collected from a donor during a platelet collect procedure before a warning is generated. If the default value of 12% is not acceptable, enter another value between 1% and 15% and press ENTER.

Press CLEAR once to return to the *total plasma collect selection message.*

Press CLEAR twice to return to the *second configuration selection message.*

- **Plasma Volumes Entry Message** (Used for TPE procedures only)

Enter number of patient plasma volumes for Plasma Exchange: {1.0}

- Press ENTER = displayed value is entered as the number of patient plasma volumes to use for initial calculations in therapeutic plasma exchange procedures. Either press ENTER to accept default value of 1.0 patient plasma volume, or enter another value between 0.2 and 5.0 and press ENTER.

- Press CLEAR = redisplays *second configuration selection message*

One plasma volume is defined as the patient's entire plasma volume and may be calculated from the patient's height, weight, and hematocrit level. As predicted by the formula $C/Co = e^{-x}$, where C = concentration of plasma components being removed and Co is the concentration of plasma replacement fluid, the fraction (C/Co) of a substance remaining in the plasma (ignoring equilibration with the extravascular compartment) is a decrementing function of the number of plasma volumes exchanged (x). Table A-3 illustrates this formula.

Table A-3. Plasma Volumes Exchanged Versus Fraction of Substance Remaining

Plasma Volumes Exchanged	Fraction Remaining (C/Co)	% Removed
0.5	0.61	39
1.0	0.37	63
1.5	0.22	78
2.0	0.14	86
2.5	0.08	92
3.0	0.05	95

The rapidly declining proportion of patient plasma removed after exchanging 1.0 to 1.5 plasma volumes has led to the adoption of this range of replacement as safe and practical.

Reference

Dau, P.C., Ed. *Therapeutic Plasma Exchange Disease Compendium.* Lakewood, Colorado: COBE Laboratories, Inc., 1983:3-21.

- **Ratio Configuration Selection Message** (Used for ELP and Platelet collection procedures only)

```
Select Inlet/AC ratio configuration:
1 = Low, 2 = Medium, 3 = High. (now ___)
```

(ENTER LED is flashing.)

When this message is first displayed, "Low," "Medium," or "High" will appear following the "now" – for example, "(now Low)" – to indicate the current inlet:AC ratio. The "medium" AC ratio configuration is pre-set for the Spectra system at the factory. For more information on the AC ratio configuration, see the **AC Ratio Configuration** subsection of the **SETTING CONFIGURATION VALUES** section of SECTION 1 – INTRODUCTION. This subsection includes a table that lists the inlet:AC ratios at each AC configuration for specific donor hematocrits.

- Press 1 = use "Low" AC ratio configuration to determine inlet:AC ratio for donor's specific hematocrit
- Press 2 = multiply "Low" inlet:AC ratio by 1.33 to determine inlet:AC ratio for donor's specific hematocrit
- Press 3 = multiply "Low" inlet:AC ratio by 1.67 to determine inlet:AC ratio for donor's specific hematocrit

- Press CLEAR = redisplays *second configuration selection message*

If the inlet:AC ratio is changed during a run, a one-time "Ratio Configuration Changed" warning will be generated at the start of the next run. See SECTION 11 - TROUBLESHOOTING.

- **Third Configuration Selection Message**

Configuration: 1 = high flow, 2 = step down, 3 = SN.

(ENTER LED is off.)

- Press 1 = displays *high flow selection message*
- Press 2 = displays *centrifuge step down selection message*
- *Press 3* = displays *single-needle option selection message* if Single-Needle Option software is present on your Spectra system
- Press CLEAR = redisplays *first configuration selection message*

- **High Flow Selection Message** Used for dual-needle ELP and Platelet collection procedures only)

High flow protocol: 1 = On, 2 = Off. (now ___)

(ENTER LED is flashing.)

When this message is first displayed, "On" or "Off" will appear following the "now" - for example, "(now on)" - to indicate whether the high flow protocol is currently activated.

- Press 1 = enables high flow to improve platelet collection
- Press 2 = disables high flow
- Press CLEAR = redisplays *third configuration selection message*

If centrifuge step down is enabled when the high flow protocol is not in effect and you then enable high flow (press 1 to turn it on), the centrifuge speed will increase to 2400 rpm and centrifuge step down will be automatically disabled. (See *centrifuge step down selection message* below.)

- **Centrifuge Step Down Selection Message**

Centrifuge step down: 1 = On, 2 = Off (now ___)

(ENTER LED is flashing.)

When this message is first displayed, "On" or "Off" will appear following "now" - for example, "(now On" - to indicate that centrifuge step down is enabled.

- Press 1 = enables centrifuge step down for platelet collect procedures
- Press 2 = disables centrifuge step down
- Press CLEAR = redisplays *third configuration selections message*

Centrifuge step down can be enabled or disabled for the current procedure as well as for subsequent procedures. To improve platelet yield, centrifuge step down can be turned on at any time up to 30 minutes into the Run mode. However, enabling centrifuge step down may increase the likelihood of spill-over occurring.

The centrifuge rpm step down occurs as follows:

Time in Run Mode (minutes)	Centrifuge Speed (rpm)
0	2400
25	2200
50	2000

If centrifuge step down is enabled when high flow has not been enabled and you then turn on high flow (see *high flow selection message* above), the centrifuge speed will increase to 2400 rpm and centrifuge step down will be automatically disabled.

- **Single-Needle Option Selection Message**

Spectra systems that are shipped with the Single-Needle Option come with the single-needle software present but not installed. Use the following selection message to install that software when you are ready to begin running single-needle ELP, Platelet, or TPE procedures. The software remains installed until you use the selection message below to deactivate it.

If you ever stop using single-needle procedures, you would also use this selection message to deactivate the Single-Needle Option.

Single needle installed? 1 = Yes, 2 = No. currently XXX installed.

(ENTER LED is flashing.)

The last line of the message will read "currently NOT installed" when the Single-Needle Option is not activated and "currently installed" when it is activated.

- Press 1 = installs Single-Needle Option
- Press 2 = deactivates the Single-Needle Option
- Press CLEAR = redisplays *third configuration selection message*

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Option 7 = Single-Needle Messages (Chosen From *First Option Selection Message*)

- **Single-Needle Statistics Message**

AC	Inlet	Plasma	Collect / Replace	Inlet : AC Ratio	Spin RPM

```
___.___ ___.___ ___.___ ___.___ instantaneous
Access:- _______ Return:-_______ (mmHg)
```

This message will display only if the system is currently running a single-needle procedure. It displays the current actual or instantaneous flow rates of the pumps and the current access and return pressures.

- **Single-Needle Conversion Option Message**

```
Press 1 to convert this run to a
single needle procedure.
```

(ENTER LED is off.)

This message is displayed only

- If the system is running a dual-needle procedure that can be converted to a single-needle procedure (Single-Needle Option installed and activated and set type Platelet or TPE selected) and
- If you have not already requested a conversion to a single-needle procedure.

To respond to the *single-needle conversion option message*:

- Press 1 = tells system to display the necessary message for conversion from a dual-needle procedure to a single-needle procedure at the appropriate time during the current procedure
- Press CLEAR = redisplays *first option selection message*

During some operation modes, the conversion of a dual-needle procedure to a single-needle procedure will be immediate. During other states, the system will store the fact that single-needle conversion must be done when the Prime mode has been completed and will display the following message:

```
Single-needle accepted. Conversion to
SN will occur after Prime.
```

For information on the steps involved in converting a Platelet or TPE procedure begun as a dual-needle procedure to a single-needle procedure, see the **DUAL-NEEDLE TO SINGLE-NEEDLE CONVERSION PROCEDURES** section in SECTION 12 – RECOVERY PROCEDURES.

- **Single-Needle Backout Option Message**

Single-needle conversion pending. Press 1 to cancel SN.

(ENTER LED is off.)

This option is displayed only

- If you have already requested a dual-needle to single-needle conversion and
- If the conversion has not yet taken place because the Prime mode has not yet finished.

To respond to the *single-needle backout option message*:

- Press 1 = tells system to cancel a previously requested dual-needle to single-needle conversion
- Press CLEAR = redisplays *first option selection message*

For detailed information on how to back out of a single-needle Platelet or TPE procedure, see the **SINGLE-NEEDLE TO DUAL-NEEDLE BACKOUT PROCEDURE** in SECTION 12 – RECOVERY PROCEDURES.

B-Data Input

APPENDIX B

DATA INPUT LIMITS

Each of the operator-selectable parameters in the COBE Spectra™ Apheresis System, and a few of the other calculated variables, have maximum and minimum warning and safety limits. For each parameter, up to six different limits may be set as follows: high and low warning limits; maximum and minimum safety limits (Automatic operation); maximum and minimum absolute limits (Manual operation).

When any parameter strays outside of its warning limits (in Automatic or Manual), a warning message will be displayed and a warning alarm (a fast triple beep) will sound. This informs you that the Spectra system is being operated outside of the manufacturer's recommended ranges. If the Spectra system is not in Manual, it will not allow you to change a parameter beyond the automatic safety limit. You will have to press the MANUAL key, going into Manual, to go beyond the automatic safety limit. **Under no circumstances, even in Manual operation, will the parameter be allowed to exceed the absolute limits.**

These limits apply whether you directly changed the parameter in question or whether the parameter was modified as a side effect of a change you made. For example, if you change the inlet pump flow rate, and the Spectra system calculates that the change will cause the projected patient platelet post-count to drop below its low warning limit, you will receive an appropriate warning message. As another example, if you change the inlet pump flow rate and the Spectra system calculates that the change will cause the AC flow rate to exceed its safety limit, it automatically reduces the inlet pump flow rate to maintain the AC flow at the safety limit and displays a warning message.

The parameters are divided into four categories:
1. Parameters that may be directly set during donor/patient data entry. (See Table B-1.)
2. Parameters that may be directly set during the Run mode, using the display keys.
3. Configuration values entered during configuration selection, using the menu system.
4. Algorithm parameters that are indirectly calculated, but still need limits.

Table B-1. Donor/Patient Data Entry Limits

Parameter	Initial Setting	Maximum Absolute Limit	Minimum Absolute Limit
Height (ft, in, or cm)	0 = no default	84 in. or 220 cm	12 in. or 30 cm
Weight (lbs or kg)	0 = no default	500 lbs or 230 kg	10 lbs or 5 kg
Donor/patient initial hematocrit (%)	45 for male, 41 for female	70	10
Donor platelet pre-count (per microliter)	250,000	2,000,000	1,000
Target collect bag volume (ml)		9999	10
Target platelet concentration in collect bag (per microliter)	1,400,000	8,000,000	100,000
Target run time (min)	100	999	10
Inlet pump flow rate (ml/min)	Inlet:AC Ratio x Q_{AC}	Dual Needle: Lower of 150 or Inlet:AC Ratio x 12 SN-ELP, SN-Platelet: 50 SN-TPE:60*	10**
Desired TPE fluid balance (%)	100	150	75
Volume of replace fluid to be used for TPE (ml)		9999	100
Volume of plasma + AC to remove for TPE (ml)		9999	100
RBCX replacement fluid hematocrit (%)	80	99	0
RBCX end hematocrit (%)	0 = no default	70	9
Desired fraction of red cells remaining (%)	0 = no default	100	1

* The maximum inlet flow rate for single-needle TPE procedures can be even lower if necessary to prevent the instantaneous flow rate from exceeding 150 ml/min.

** For special recovery procedures, 0 (zero) can be entered to stop the inlet pump.

Table B-1, Cont. Donor/Patient Data Entry Limits

Parameter	Initial Setting	Maximum Absolute Limit	Minimum Absolute Limit
RBC replacement volume (ml)	0	9999	100
Access pressure low limit (mmHg)	–250	–250	–50
Return pressure high limit (mmHg)	400	400	50

C-Manual &
Automatic

APPENDIX C

MANUAL AND AUTOMATIC OPERATION

The COBE Spectra™ Apheresis System is capable of operating under Manual or Automatic control.

NOTE

During WBC procedures, when you switch from Manual operation to Automatic operation, the inlet:AC ratio and the subject's hematocrit are reset to their default values: Default inlet:AC ratio = 12:1 for MNC procedures and 13:1 for PMN procedures, default hematocrit = 45 for males and 41 for females.

MANUAL RUN OPERATION

Each procedure can be run in Manual operation once the tubing set has been primed. Donor/patient data do not have to be entered. Instead, the MANUAL key can be pressed, allowing you to set the run parameters. The Spectra system proceeds to run in Manual operation immediately. A message appears (see below), warning that Automatic operation will not be allowed throughout the entire procedure unless donor/patient data are entered. If donor/patient data are entered later in the procedure, the Spectra system proceeds to run in Automatic operation immediately for the remainder of the run.

Procedure will be run in Manual.
Automatic not valid until data entry.

Following is a description of how the FLOW, RATIO, and SPIN keys function in Manual operation:

CAUTION

No pump flow rates are controlled automatically when the Spectra system is in Manual operation.

In Manual operation, flow rates can be entered that are outside of the performance specifications described in SECTION 14 - SPECIFICATIONS. COBE makes no accuracy claim for values outside the specified performance range for each pump.

AC FLOW The flow rate range of the AC pump is 1 to 12 ml/min. Changes in the AC pump flow rate will not change the inlet pump flow rate, but will cause the inlet:AC ratio to be recalculated.

INLET FLOW The flow rate range of the inlet pump is 10 to 150 ml/min. Changes in the inlet pump flow rate will not change the AC pump flow rate, but will cause the inlet:AC ratio to be recalculated. For special recovery procedures a minimum

inlet flow rate of 0 (zero) can be entered to stop the inlet pump. The maximum 150 ml/min for the inlet flow rate applies to dual-needle procedures only. For those procedures, the maximum inlet flow rate is 150 ml/min or the inlet:AC ratio x 12, whichever is the smaller. For single-needle ELP or Platelet procedures, the maximum inlet flow rate is 50 ml/min; for single-needle TPE procedures, it is 60. The maximum inlet flow rate for single-needle TPE procedures can be even lower, if necessary, to prevent the instantaneous flow rate from exceeding 150.

PLASMA/RBC FLOW

The flow rate range of the plasma/RBC pump is 2 to 100 ml/min. The plasma/RBC pump flow rate can be changed independently. Changes in this flow rate will affect the hematocrit in the RBC line as follows:

Increase plasma pump flow rate = increased hematocrit in RBC line
Decrease plasma pump flow rate = decreased hematocrit in RBC line

For RBCX procedures, pressing the PLASMA FLOW key changes the red blood cell flow instead of the plasma flow.

COLLECT/ REPLACE FLOW

The flow rate range of the collect/replace pump is 1 to 100 ml/min. The collect/replace pump flow rate can be changed independently. Changes in this flow rate will affect the cell concentration in a collection and the fluid balance in a TPE and RBCX procedure.

INLET:AC RATIO

The direct ratio limit (the limit that can be changed by the operator) is between 3 and 50. Changes in ratio will change the inlet pump flow rate only (inlet pump flow rate = inlet:AC ratio x AC pump flow rate). The AC pump flow rate remains the same. Changes to the AC pump flow rate or the inlet pump flow rate can cause an allowable ratio change between 2 and 100.

SPIN RPM

The centrifuge speed range is 400 to 2400 rpm. The centrifuge speed can be changed independently in Manual operation.

AUTOMATIC RUN CHANGES

Following is a description of how the FLOW, RATIO, and SPIN keys function in relation to changes during Automatic operation:

AC FLOW

No direct change is allowed using the AC FLOW key.

INLET FLOW

When the inlet pump flow rate is changed, the inlet:AC ratio is maintained. Therefore, the AC pump flow rate changes in the same direction as the inlet pump flow rate. The inlet pump flow rate may be increased until the AC infusion rate limit of 1.2 ml/min/liter of TBV is reached. If the inlet pump flow rate is increased to the point that the AC infusion rate exceeds 1.2 ml/min/liter of TBV, the "AC infusion rate exceeds allowable limits" alarm will occur. See SECTION 11 – TROUBLESHOOTING for details on that alarm.

PLASMA/RBC FLOW

For ELP, Platelet, and TPE procedures, no direct change is allowed using the PLASMA FLOW key. Plasma flow will change automatically to maintain proper blood component separation.

For WBC procedures, the plasma flow can be changed directly using the PLASMA FLOW key.
For RBCX procedures, pressing the PLASMA FLOW key changes the red blood cell flow instead of the plasma flow.

COLLECT/ REPLACE FLOW

No direct change is allowed using the COLLECT/REPLACE FLOW key.

INLET:AC RATIO

The ratio can be changed between a low ratio of 3:1 to a high ratio of 50:1. Changes in ratio will change inlet pump flow rates only. AC pump flow rates remain the same. The relationship between the inlet:AC ratio and the donor's/patient's hematocrit can be configured to be "low" (standard, factory-set relationship), "medium" (1.33 x "low"), and "high" (1.67 × "low"). For the keystrokes to configure the inlet:AC ratio, see the ratio configuration selection message in APPENDIX A - KEYBOARD SELECTIONS. For information on the inlet:AC ratios for selected hematocrits for "low," "medium," and "high" configuration settings, see the discussion of AC Ratio Configuration in the **SETTING CONFIGURATION VALUES** section of SECTION 1 - INTRODUCTION.

SPIN RPM

No direct change is allowed using the SPIN RPM key. The centrifuge speed will automatically change for TPE, RBCX, and WBC procedures when a change in the inlet pump flow rate is selected and a new separation factor is required for the appropriate blood separation.

SINGLE-NEEDLE FLOW CONTROL

For single-needle ELP, Platelet, and TPE procedures, any direct or indirect change to pump flow rates during either Manual or Automatic operation has an immediate effect on the instantaneous flow rate. Depending upon the direction of the change made to a pump flow rate during a single-needle draw phase, the length of the draw phase may increase or decrease. In fact, some changes in pump flow rates during a draw phase would make the draw phase stop and the return phase immediately start. For example, if you decrease the inlet flow rate in the middle of a single-needle draw phase to the point that the single-needle bag has reached its algorithm volume, the Spectra system would immediately enter the single-needle return phase.

During single-needle procedures, you can carry out most Manual operation changes, such as stopping the collect/replace pump or stopping both the plasma pump and the collect/replace pump, and the normal single-needle cycle will continue with that pump or pumps stopped.

In Manual operation, you can ask for combinations of average flow rates that cannot be achieved during single-needle operation. If you make any change in Manual operation that is beyond the capabilities of a single-needle procedure, such as reducing the inlet flow rate to zero, a special mode of Manual operation is invoked.

The special Manual mode is announced by a triple beep. If you are in a draw phase, it will be aborted, the return valve will open, and the AC and inlet pumps will be stopped. Then, while the Return Flow Controller is returning the contents of the single-needle bag to the donor/patient, you will have direct control of the plasma and collect/replace pumps. This means that when you enter an average flow rate for one of these pumps, it will instead become an immediately commanded instantaneous flow rate.

As soon as conditions allow a normal single-needle cycle to recommence (for example, entering a different flow rate or returning to Automatic operation), this special Manual mode is discontinued, all pumps are stop, and the return phase is allowed to proceed from where it left off.

COOK, McFARRON & MANZO
A PROFESSIONAL CORPORATION
ATTORNEYS AND COUNSELORS AT LAW
135 SOUTH LA SALLE STREET · SUITE 4100
CHICAGO, ILLINOIS 60603

GRANGER COOK, JR.
STEPHEN B. HELLER
ANDREW G. KOLOMAYETS
EDWARD D. MANZO
GARY W. MCFARRON
MARK J. MURPHY
OF COUNSEL
DONALD E. EGAN

TELEPHONE
(312) 236-8500
FACSIMILE
312-236-8176

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June 13, 1996

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RYAN, MAKI, MANN & HOHENFELDT

VIA FEDERAL EXPRESS
Daniel D. Ryan, Esq.
RYAN, MAKI, MANN & HOHENFELDT, S.C.
Suite 1900
633 W. Wisconsin Avenue
Milwaukee, Wisconsin 53203

Re: **Cobe Spectra Manuals**

Dear Dan:

Per your request, enclosed please find the following:

1. Cobe Spectra Operator's Manual for software program revisions 2.0 through 2.9;

2. Cobe Spectra Operator's Manual for software program revisions 3.0 through 3.9, and

3. Cobe Spectra Inservice Program Presenter's Guide.

If you have any questions regarding the above, please do not hesitate to call.

Sincerely,

Andy

Andrew G. Kolomayets

AGK/dh
Encl.
cc: Gary W. McFarron